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Patent Law: A Primer and Overview of Emerging Issues

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Summary

In an increase over prior terms, the Supreme Court of the United States issued six opinions involving patent law during its October 2016 Term. These decisions addressed issues ranging from patent exhaustion, multicomponent products, and biosimilar patents to procedural issues like venue and the statute of limitations for infringement claims. The growing number of Supreme Court opinions involving patent law over the past decade may also speak to the rising importance of intellectual property more broadly; a reported 84% of the S&P 500 Market Value in 2015 is ascribed to intangible assets. With this increased attention on patent law, an understanding of patent law and the cases issued during the High Court's recently concluded term will likely be of interest to Congress.

The patent law regime in the United States is grounded in the U.S. Constitution itself; article I, section 8, clause 8 of the Constitution provides: "The Congress Shall Have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries." Nonetheless, the rights associated with patents do not arise automatically. Rather, to obtain patent protection, the Patent Act of 1952 requires inventors to apply with the U.S. Patent and Trademark Office (PTO).

A patent may be obtained by "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter," subject to the requirements of the Patent Act. A valid patent bestows upon its holder the right to take action against anyone who "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent," unless authority to do so is secured from the patent holder. In addition to examining patent applications, the PTO conducts other proceedings to determine the validity of issued patents, which can result in the revocation of previously issued patents. These proceedings play a central role in the country's patent system. Final decisions from the PTO are appealable to the U.S. Court of Appeals for the Federal Circuit, which has exclusive, nationwide jurisdiction over most patent appeals.

With the Supreme Court hearing an increasing number of cases involving patent law and other areas of intellectual property over the last decade, the Court is playing a larger role in the development of patent law. During its October 2016 Term, the Court issued two patent law opinions involving procedural issues that will affect *when* and *where* patent cases may be filed. In another pair of cases heard during the October 2016 Term, the High Court dealt with issues related to patents on multicomponent products—one in the context of determining infringement and another in the context of calculating damages. A final pair of patent cases decided during the Term may have major implications for the pharmaceutical industry—one addresses whether post-sale restrictions, commonly used in the pharmaceutical industry, are enforceable under patent law, and the other will likely affect the speed at which biosimilars come to market.

In addition to the effects of the Supreme Court's patent decisions issued during its October 2016 Term on patent law, there are a number of patent-related issues on the horizon. The constitutionality of one of the PTO's post-grant review proceedings has been called into question in a case that will be heard during the Court's upcoming October 2017 Term. In addition, with patent reform being of perennial concern to Congress, certain legislative proposals have the potential to alter various areas of patent law.

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Introduction

In an increase over prior terms, the Supreme Court of the United States issued six opinions involving patent law during its October 2016 Term.[1] These decisions addressed issues ranging from patent exhaustion,[2] multicomponent products,[3] and biosimilar patents[4] to procedural issues like venue[5] and the statute of limitations for infringement claims.[6] The increase in patent cases heard by the High Court coincides with an apparent increase in patent litigation generally. As observed by Judge Kathleen O'Malley of the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), the court that has exclusive jurisdiction over most appeals involving patents: "While federal filings in complex civil cases in regional circuits have been down in recent years, the patent litigation business is booming. Indeed, patent filings in district courts have almost doubled from 2010—when there were 3,301 patent actions filed—to 2013, when ... there were 6,497 such cases instituted."[7]

The increase in patent litigation may reflect a broader interest in patents generally. As Judge Timothy Dyk, also of the Federal Circuit, has written: "[P]atent law has ... moved further into the mainstream. And the importance of intellectual property to the broader American economy has continued to grow, with an estimated 84% of the S&P 500 Market Value attributable to intangible assets in 2015."[8] Another commentator has noted that "patent law is indisputably more visible to lawyers and to the general public today than it was a decade or two ago. Stories about patent law, patent litigation, and even the Federal Circuit itself are regular fixtures of leading newspapers...."[9] Accordingly, an understanding of patent law and the cases issued during the Supreme Court's recently concluded October 2016 Term will likely be of interest to Congress.

To this end, this report begins with an overview of patent law. It then discusses the Supreme Court's role in the development of patent law generally before examining the Court's recent decisions in detail. Finally, the report closes with a preview of developments in patent law that are on the horizon, such as the continued viability of certain administrative proceedings related to the

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[1] *See* Hon. Timothy B. Dyk, *Thoughts on the Relationship Between the Supreme Court and the Federal Circuit*, 16 CHI.-KENT J. INTELL. PROP. 67, 67 (2016), *available at* http://scholarship.kentlaw.iit.edu/ckjip/vol16/iss1/3 ("In the past ten years, the Supreme Court has taken an average of four of [the U.S. Court of Appeals for the Federal Circuit's] cases each term.... A large proportion of those cases have involved substantive patent law or related procedural issues.").

[2] Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017).

[3] Life Techs. Corp. v. Promega Corp., 137 S. Ct. 734 (2017); Samsung Elecs. Co. v. Apple Inc., 137 S. Ct. 429 (2016).

[4] Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017).

[5] TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514 (2017).

[6] SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 137 S. Ct. 954 (2017).

[7] Hon. Kathleen M. O'Malley, *The Intensifying National Interest in Patent Litigation*, 19 MARQ. INTELL. PROP. L. REV. 1, 3–4 (2015), *available at* http://scholarship.law.marquette.edu/iplr/vol19/iss1/2 (noting "the Federal Circuit's shift from a relatively little-known court to one whose work in the [intellectual property] field has become the focus of all three branches of government, an increasing number of increasingly vocal academics in the field, reporters, and ... bloggers").

[8] Dyk, *supra* note 1, at 83; *see also* O'Malley, *supra* note 7, at 6 (noting that "patent litigation has become more mainstream").

[9] Paul Gugliuzza, *How Much Has the Supreme Court Changed Patent Law*, 16 CHI.-KENT J. INTELL. PROP. 330, 335 (2017), *available at* http://scholarship.kentlaw.iit.edu/ckjip/vol16/iss2/5 (footnote omitted); *see also id.* at 333–34 ("In short, despite patent law's reputation as a specialized area of practice, the field is plainly no longer, as it was once derisively described, the domain of only 'people wearing propeller hats.'" (quoting Hon. Kimberly A. Moore, *Are District Judges Equipped to Resolve Patent Cases?*, 15 HARV. J. L. TECH. 1, 11 (2001))).

validity of patents, which is the subject of two cases scheduled to be heard during the Court's upcoming term, as well as patent reform activity in the legislative and executive arenas.

Overview of Patent Law

The patent law regime in the United States is grounded in the U.S. Constitution itself; article I, section 8, clause 8 of the Constitution provides: "The Congress Shall Have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries."[10] Nonetheless, the rights associated with patents do not arise automatically. Rather, to obtain patent protection, the Patent Act of 1952[11] requires inventors to file a patent application with the PTO.[12]

Requirements for Obtaining a Patent

A patent[13] may be obtained by "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," subject to the requirements of the Patent Act.[14] A valid patent bestows upon its holder a time-limited "franchise granting the right to exclude everyone from making, using or selling the patented invention without the permission of the patentee."[15] This right to exclude is enforceable under the Patent Act, which states that anyone who "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent ... infringes the patent" unless authority to do so is secured from the patent holder.[16]

The administrative process of applying for and acquiring a patent before the PTO is called "patent prosecution."[17] Once an inventor files a patent application, a patent examiner at the PTO will evaluate whether the application meets the requirements of the Patent Act and thus merits the

[10] U.S. CONST. art. I, § 8, cl. 8.

[11] Pub. L. No. 82-593, 66 Stat. 792 (codified at U.S.C. Title 35).

[12] 35 U.S.C. § 111.

[13] This discussion chiefly addresses so-called "utility patents," although the procedures and concepts discussed generally apply to all three types of patents the PTO issues: (1) "utility patents," as described above; (2) "design patents," which are granted to inventors of new, original, and ornamental designs for articles of manufacture; and (3) "plant patents," which are granted to those who invent or discover, and asexually reproduce, any distinct and new variety of plant. *See General Information Concerning Patents*, U.S. PATENT & TRADEMARK OFFICE (Oct. 2015), https://www.uspto.gov/patents-getting-started/general-information-concerning-patents [hereinafter *PTO General Information*]. For a description of design patents in particular, see discussion *infra* in *Cases Involving Multicomponent Products*: *Samsung Electronics v. Apple*.

[14] *Id.* § 101 (emphasis added).

[15] Reeves Bros. v. U.S. Laminating Corp., 282 F. Supp. 118, 134 (E.D.N.Y. 1968), *aff'd*, 417 F.2d 869 (2d Cir. 1969); *see also* Bloomer v. McQuewan, 55 U.S. 539, 549 (1852) ("The franchise which the patent grants, consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee. This is all that he obtains by the patent.").

[16] 35 U.S.C. § 271(a).

[17] *See generally PTO General Information*, *supra* note 13.

award of a patent.[18] Under the Act, the application must include a written "specification."[19] The specification must include:

> a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art[20] to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the *best mode* contemplated by the inventor or joint inventor of carrying out the invention.[21]

In other words, the Patent Act requires that a specification meet: (1) the *written description requirement*, which is met when a specification "'reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date'" of the patent;[22] (2) the *enablement requirement*, under which "the specification ... must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'";[23] and (3) the *best mode requirement*, which requires that the specification demonstrates that "the inventor possessed a best mode of practicing the claimed invention at the time of filing the patent application."[24]

The Patent Act further requires that the specification "conclude with one or more *claims* particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."[25] Patent claims define the parameters of what an inventor considers his or her invention. As the Federal Circuit has noted:

> The function of claims is (a) to point out what the invention *is* in such a way as to distinguish it from what was previously known ... and (b) to define the *scope of protection* afforded by the patent. In both of those aspects, claims are not technical descriptions of the disclosed inventions but are legal documents like the descriptions of lands by metes and bounds in a deed which *define the area* conveyed but *do not describe the land*.[26]

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[18] *Id.* § 131 ("The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.").

[19] *Id.* § 111(a)(2).

[20] The "person skilled in the art" is an important legal fiction in the field of patent law, perhaps akin to the "reasonable person" in tort law. *See* Beck by Chain v. Thompson, 818 F.2d 1204, 1218 (5th Cir. 1987) (describing "the reasonably prudent person" as "the mythical man of legal fiction"). The person of ordinary skill in the art is neither a layperson nor a genius. *See* Envtl. Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 697 (Fed. Cir. 1983) ("The important consideration lies in the need to adhere to the statute, *i.e.*, to hold that an invention would or would not have been obvious, as a whole, when it was made, to a person of 'ordinary skill in the art'—not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand."). The Supreme Court has clarified, however, that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

[21] 35 U.S.C. § 112(a) (emphases added); Tobinick v. Olmarker, 753 F.3d 1220, 1225–26 (Fed. Cir. 2014) ("The purpose of the written description requirement is to require an inventor to disclose his invention to the public in such a manner as to allow 'a person of skill in the art to recognize that the patentee invented what is claimed.'" (quoting Synthes USA, LLC v. Spinal Kinetics, Inc., 734 F.3d 1332, 1341 (Fed. Cir. 2013))).

[22] Rivera v. Int'l Trade Comm'n, 857 F.3d 1315, 1319 (Fed. Cir. 2017) (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).

[23] Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1360 (Fed. Cir. 2007) (quoting *In re* Wright, 999 F.2d 1557, 1561 (Fed.Cir.1993)).

[24] Star Sci., Inc. v. R.J. Reynolds Tobacco Co., 655 F.3d 1364, 1373 (Fed. Cir. 2011) (citations omitted).

[25] 35 U.S.C. § 112(b) (emphasis added). It should be noted that "claim" is a term of art in the patent context and should not be confused with, inter alia, the claims asserted in a lawsuit.

[26] *In re* Vamco Mach. & Tool, Inc., 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985).

In addition to examining a patent application for compliance with the statute's specification requirements, the patent examiner also determines whether a patent application meets several substantive standards of the Patent Act. Namely, to be patentable, an invention must be (1) a "process, machine, manufacture, or composition of matter"[27] that is (2) novel, (3) useful, and (4) nonobvious. A corollary to the first requirement that "specifies four independent categories of inventions or discoveries that are eligible for protection"[28] is that there is certain subject matter that is ineligible for patent protection; three specific examples of unpatentable subject matter that the Supreme Court has articulated are "laws of nature, physical phenomena, and abstract ideas."[29] As to novelty, the Act provides that a patent cannot be issued if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention."[30] That is, the invention must be something new and different as compared to the so-called "prior art," which are the existing references that disclose the state of the art, such as publications and other patents.[31] As to usefulness or utility, the patent application must demonstrate that the "claimed invention has a significant and presently available benefit to the public ... which is not so vague as to be meaningless."[32] Finally, as to nonobviousness, the Act provides that "[a] patent for a claimed invention may not be obtained ... if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."[33] In other words, "a patent may be found invalid as obvious if 'there are a finite number of identified, predictable solutions, [and] a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.'"[34]

Rights of Patent Holders

With some exceptions,[35] a patent is generally granted "for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed."[36] Notably, once this period expires, others may use the invention without regard to the expired patent. During the term of a patent, however, anyone who "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent ... infringes the patent" unless authority to do so is secured from the patent holder.[37] Patent rights, however, are not self-enforcing; rather, patent

[27] 35 U.S.C. § 101.

[28] Bilski v. Kappos, 561 U.S. 593, 601 (2010).

[29] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). "While these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be 'new and useful.'" *Bilski*, 561 U.S. at 601–02.

[30] 35 U.S.C. § 102(a).

[31] *Id.* § 102.

[32] *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

[33] 35 U.S.C. § 103.

[34] Trivascular, Inc. v. Samuels, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (quoting KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007)).

[35] 35 U.S.C. § 154(a)(2). The Patent Act includes provisions that may modify the twenty-year term, including, for example, to account for examination delays at the PTO or delays associated with obtaining marketing approval from other federal agencies. *Id.* § 154(b).

[36] *Id.* § 154(a).

[37] *Id.* § 271(a). In addition, those who "actively induce[ ] infringement of a patent shall be liable as an infringer." *Id.* § 271(b).

holders must initiate enforcement measures themselves, most commonly through litigation in federal court.[38]

Although issued patents are entitled to a presumption of validity,[39] accused infringers may defend against infringement actions on several grounds, including: (1) *noninfringement* or the "absence of liability for infringement" in light of a valid license or that the patent claims, when properly construed, do not cover the allegedly infringing acts;[40] (2) *patent invalidity*, that is, that a patent is invalid for failure to meet any of the statutory requirements discussed above; [41] or (3) *unenforceability*, or that a patent is unenforceable due to, for example, inequitable conduct in obtaining the patent.[42]

There are several remedies available to the patent holder in light of a finding of infringement, and the Supreme Court has taken an active role in defining these remedies over the past decade. First, infringers can be enjoined from further infringement.[43] Until 2006, the Federal Circuit followed a "'general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.'"[44] In *eBay Inc. v. MercExchange, L.L.C.*, however, the Supreme Court clarified that courts must follow the four-factor test used in other areas of law before issuing a permanent injunction, thus heightening the requirement for injunctions in patent cases.[45]

Second, the Patent Act provides for damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[46] The Act further gives courts the discretion to "increase the damages up to three times the amount found or assessed."[47] In 2016, the Supreme Court clarified in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, that the award of such enhanced damages is "designed as a 'punitive' or 'vindictive' sanction for egregious infringement behavior,"[48] such as "willful infringement."[49] Finally, attorney fees may be awarded to the prevailing party in "exceptional cases."[50] In 2014,

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[38] *See id.* § 281 ("A patentee shall have remedy by civil action for infringement of his patent.").

[39] *Id.* § 282 (a) ("A patent shall be presumed valid.").

[40] *Id.* § 282(b)(1).

[41] *Id.* § 282(b)(2)–(3).

[42] *Id.* § 282(b)(1). "Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct." Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011).

[43] 35 U.S.C. § 283 ("The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.").

[44] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006) (quoting MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1339 (Fed. Cir. 2005)).

[45] *Id.* ("According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.").

[46] 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.").

[47] *Id.* ("[T]he court may increase the damages up to three times the amount found or assessed.").

[48] 136 S. Ct. 1923, 1932 (2016).

[49] *See* Alfred E. Mann Found. v. Cochlear Corp., 841 F.3d 1334 (Fed. Cir. 2016).

[50] 35 U.S.C. § 285.

the Supreme Court clarified in *Octane Fitness, LLC v. Icon Health & Fitness Inc.*, that an "exceptional case" is "one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated" based on the "totality of the circumstances."[51]

Major Patent Legislation

As discussed below, patent reform appears to be of perennial interest to Congress, particularly over the last few decades.[52] While a comprehensive history of legislative activity in the patent area is beyond the scope of this report, there are several key pieces of legislation enacted since the passage of the Patent Act of 1952 that merit mention.[53]

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, which amended both patent law as well as food and drug law.[54] The Hatch-Waxman Act included provisions intended to facilitate the marketing of generic pharmaceuticals, while incentivizing brand-name firms to innovate. For example, abrogating then-prevailing case law,[55] the Act allowed potential generic drug manufacturers to obtain marketing approval from the Food and Drug Administration (FDA) on a patented drug by relying on the safety and efficacy data of an approved drug, while the patent holder, in turn, receives a period of regulatory exclusivity.[56] In other words, the Act allowed generic manufacturers to commence work on a generic version of an approved drug during the life of the patent if the work complies with FDA regulations. In 2009, Congress enacted a related statute called the Biologics Price Competition and Innovation Act of 2009, which established procedures for "biologics"—a category of medical preparations derived from a living organism—that are found to be "biosimilar" or interchangeable with an FDA-approved biologic.[57] Both of these laws are discussed in more detail below.[58]

The most recent patent reform legislation, and perhaps the one that has made the most significant changes to patent law in the modern era, is the Leahy-Smith America Invent Act (AIA), signed into law in September 2011.[59] Among the significant changes the AIA made to the patent system is the so-called "first to file rule," under which the first inventor to file a patent application

[51] 134 S. Ct. 1749, 1756 (2014). In a companion case issued the same day as *Octane Fitness*, the Supreme Court held that the Federal Circuit must review a district court's award of attorney fees under an abuse-of-discretion standard. Highmark, Inc. v. Allcare Health Mgmt. Sys. Inc., 134 S. Ct. 1744 (2014), thus decreasing the likelihood of an award being overruled on appeal.

[52] *See* discussion *infra* in *Legislative and Executive Patent Law Activity*.

[53] Other notable legislation, albeit with a smaller impact, includes the American Inventors Protection Act of 1999, P.L. 106-113, 113 Stat 1501 (1999), which mainly addressed certain PTO procedures, and the Patent and Trademark Law Amendments Act, P.L. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. §§ 200–12), commonly termed the Bayh–Dole Act, which concerned ownership issues related to inventions that benefit from federally-funded research.

[54] P.L. 98-417, 98 Stat. 1585 (1984).

[55] Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984) (holding that a generic drug manufacturer's research activities conducted prior to the expiration of a drug's patent constituted infringement).

[56] 35 U.S.C. § 271(e)(1).

[57] P.L. 111-148, 124 Stat. 804 (2010). *See also* CRS Report R44173, *Follow-On Biologics: Intellectual Property Issues*.

[58] For a more detailed discussion of Hatch-Waxman and the Biologics Price Competition and Innovation Act, see discussion *infra* in *Cases with Implications for the Health Care Industry*.

[59] P.L. 112-29, 125 Stat. 284–341 (2011).

prevails when two or more persons independently develop the identical or similar invention at approximately the same time.[60] This change brought the United States into conformity with all other patent-issuing countries, thereby arguably facilitating better cross-border cooperation in the patent arena.[61] In addition, the AIA established assignee filing, which allows an inventor's employer or other entity to which patent rights are assigned to file patent applications, in contrast to the previous rule that the natural person or persons who developed an invention must file the patent application, even where the invention was developed in the inventor's capacity as an employee.[62]

Perhaps most significantly, as explained in more detailed in the following section, the AIA established or modified various administrative challenges to the validity of an issued patent before the PTO,[63] including (1) *post-grant review*, which allows petitioners to challenge patent validity for failure to meet any of the Patent Act's patentability requirements for a patent, such as ineligible subject matter or lack of enablement;[64] (2) *inter partes review*, which replaced the former inter partes reexamination system;[65] (3) *supplemental examination*, which allows patent holders to request an examination to "consider, reconsider, or correct information believed to be relevant to the patent";[66] and (4) a *transitional program for covered business method patents*, which is a temporary program for a subset of patents involving certain "covered business methods" that operate similarly to post-grant reviews, but will only be available through September 2020 under a sunset provision in the AIA.[67]

While there have not been substantial changes made to patent law through legislation since the enactment of the AIA, as discussed below, there remains the possibility of future changes.[68] As

[60] Prior to the enactment of the AIA, the United States was the only patent-issuing country to follow the "first to invent rule." *See* 35 U.S.C. § 100 note ("It is the sense of the Congress that converting the United States patent system from 'first to invent' to a system of 'first inventor to file' will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.").

[61] *Id.*

[62] *Id.* § 118 ("A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent.").

[63] Prior to the AIA, the PTO administered two types of reexamination proceedings: ex parte reexaminations and inter partes reexaminations. Ex parte reexaminations were conducted between the patent holder and the PTO with no third party involvement and allowed the patent holder to cite newly discovered prior art to the PTO. If the prior art reference raised a "substantial" question of patentability, the PTO would reopen patent prosecution. Inter partes reexaminations, on the other hand, allowed any individual to cite a prior art in order to reopen patent prosecution and to participate in the proceedings as a third party. Both types of reexamination proceedings could result in either a certificate confirming the patentability of the patent's claims, an amended patent with narrower claims, or a declaration of patent invalidity.

[64] 35 U.S.C. §§ 321–29.

[65] *Id.* §§ 311–19.

[66] *Id.* § 257. Patent prosecution is conducted as an ex parte procedure between the patent applicant and the PTO (i.e., without input from third parties), *id.* § 122(a) (stating the general rule that "applications for patents shall be kept in confidence by the [PTO] and no information concerning the same given without authority of the applicant"). Patent applicants are bound to a duty of candor and truthfulness; failure to observe this duty can result in a ruling that a patent is unenforceable under the doctrine of "inequitable conduct" if an applicant intentionally misrepresents a material fact or fails to disclose material information. *See* Glaverbel Societe Anonyme v. Northlake Mktg. & Supply Inc., 45 F.3d 1550 (Fed. Cir. 1995). A supplemental examination proceeding allows patent holders to disclose newly-discovered information that could otherwise be grounds for a finding of the breach of the duty of candor, which could lead to a finding of inequitable conduct in patent litigation.

[67] P.L. 112-29, § 18, 125 Stat 284, 329–30 (2011) (not codified in U.S.C.).

[68] *See* discussion *infra* in *Legislative and Executive Patent Law Activity*.

well, certain cases before the federal courts have the potential to invalidate some provisions of the AIA, such as those providing for inter partes review proceedings.[69]

Administrative Proceedings Before the PTO

As is evident, in addition to patent prosecution, the PTO conducts other administrative review proceedings, including those provided for in the AIA. Most of these proceedings involve challenges to the validity of issued patents and may result in the revocation of a previously issued patent. Such proceedings play a central role in the country's patent system as a popular, "less expensive and quicker alternative to litigation."[70]

A post-grant review,[71] made available under the AIA, allows petitioners to challenge a patent's validity based on any ground of patentability, but must be filed *within* nine months of the date the patent was granted.[72] After a petition for a post-grant review is filed, the patent holder has the opportunity to file a response arguing that the post-grant review should not be initiated.[73] If such a review is initiated, however, the PTO's Patent Trial and Appeal Board (PTAB) will conduct a trial[74] and issue a final written decision,[75] which can be appealed to the federal courts.[76]

Also created by the AIA, an inter partes review allows any person (other than the patent holder) to challenge a patent based on previously issued patents or printed publications (i.e., the prior art) on

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[69] *See* discussion *infra* in *Viability of Inter Partes Review Proceedings*.

[70] *See, e.g.*, Robert Stoll, (Sept. 12, 2017), http://www.ipwatchdog.com/2017/09/12/five-years-inter-partes-review/id=87424/ ("The vast majority of the users of the patent system recognize that the original intent of [inter partes review proceedings], namely bolstering the confidence in the patent system and patent quality by establishing a quicker and cheaper method to challenge questionable patents at the [PTO], is a laudable goal and there have been numerous suggestions for improving the system to allow it to serve its purpose fairly, efficiently and effectively."); Brian C. Kwok, Nicholas V. Martini & Nicole Johnson, An Update On Post-Grant Review Filings And Decisions, LAW360 EXPERT ANALYSIS (Nov. 2, 2016), https://www.law360.com/articles/858429/an-update-on-post-grant-review-filings-and-decisions (observing "the increasing popularity of post-grant review and its role as a component of overall patent litigation strategy"); Matt Cutler, *3 Years Of IPR: A Look At The Stats*, LAW360 EXPERT ANALYSIS (Oct. 9, 2015), https://www.law360.com/articles/699867/3-years-of-ipr-a-look-at-the-stats (discerning "from the statistical trends that [inter partes review] is here to stay. Petitioners are given a favorable playing field to litigate the patentability of claims and, statistics seem to show, they are having considerable success, especially in the electrical/computer arts").

[71] 35 U.S.C. §§ 321–29. As noted, the AIA also created a post-grant review proceeding to challenge the validity of certain "covered business methods." P.L. 112-29, § 18, 125 Stat 284, 329–30 (2011) (not codified in U.S.C.). Such proceedings operate similarly to post-grant reviews but are limited to challenges to patents claiming "a method or corresponding apparatus for performing data processing operations utilized in the practice, administration, or management of a financial product or service, except that the term shall not include patents for technological inventions." *Id.* § 18(d)(1). These proceedings may only be requested by individuals accused of infringement of a business method patent. Under a sunset provision, this proceeding will no longer be available after September 16, 2020. *Id.* § 18(a)(2).

[72] 35 U.S.C. § 321(c).

[73] *Id.* § 323. *See also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012).

[74] For more information about the PTAB, see *Patent Trial and Appeal Board*, U.S. PATENT & TRADEMARK OFFICE, https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board-0 (last modified Sept. 14, 2017) ("The [PTAB] conducts trials, including inter partes, post-grant, and covered business method patent reviews and derivation proceedings, hears appeals from adverse examiner decisions in patent applications and reexamination proceedings, and renders decisions in interferences.").

[75] "For [inter partes reviews], [post-grant reviews], and [covered business method reviews], the [PTAB] will enter a final written decision not more than one year from the date a trial is instituted.... The [PTAB] expects that a final written decision will address the issues necessary for resolving the proceeding." Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,768.

[76] 35 U.S.C. §§ 326(c), 328–29.

the basis of novelty and/or nonobviousness.[77] Such petitions may be filed at least nine months *after* a patent issues or a post-grant review concludes, whichever is later.[78] As a result, a patent may be challenged administratively on any basis of patentability within nine months of the date it was granted through a post-grant review, after which it can be challenged on novelty and nonobviousness grounds through an inter partes review for the remainder of the patent's term. Both types of proceedings involve a trial-like procedure before a three-member panel,[79] and include the use of witnesses, limited discovery, and a hearing prior to a decision on the merits.[80]

Finally, reexamination proceedings, which predate the enactment of AIA, allow any person, including the patent holder or the PTO Director, to cite prior art to challenge an issued patent on novelty or nonobviousness grounds.[81] Unlike post-grant review and inter partes review proceedings, however, reexaminations effectively reopen prosecution of an issued patent and proceed on an ex parte basis (i.e., between the patent applicant and the PTO without participation by third parties).[82] In addition, reexamination proceedings result in either (1) a certificate confirming the patentability of the patent, (2) the reissue of the patent with narrowed claims, or (3) a declaration of patent invalidity.

Proceedings Before the Federal Courts

The Federal Circuit has exclusive, nationwide jurisdiction over the majority of patent appeals,[83] while the Supreme Court has discretionary authority to review cases decided by the Federal Circuit.[84] The Federal Circuit also has jurisdiction over appeals involving veterans' claims, government contracts, federal taxation, claims under the Vaccines Act, grievance claims from federal employees, appeals involving international trade matters, among others.[85] Notably, the Federal Circuit has "no criminal jurisdiction, hear[s] few constitutional issues, and almost no cases involve state-law issues."[86] This unique jurisdictional purview may be responsible for what one commentator has described as a view of the Federal Circuit, on the part of Supreme Court and the other circuit courts, "as inhabiting a world apart."[87] Some even view the Federal Circuit as a "rogue" court that is frequently reversed by the Supreme Court.[88] However, although over the last decade the reversal rate for the Federal Circuit has been above the median of the circuit courts, it has been *lower* than five of its twelve sister circuits.[89] Nonetheless, "a perceived tension

[77] *Id.* §§ 311–19.

[78] *Id.* § 311.

[79] Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,768 ("Each party to a proceeding will be afforded an opportunity to present their case before at least three members of the [PTAB].").

[80] *See id.* at 48,765–68.

[81] *Id.* §§ 302–07.

[82] *Id.* § 303.

[83] 28 U.S.C. § 1295(a)(1).

[84] *Id.* § 1254(1).

[85] *See* Gugliuzza, *supra* note 9, at 1437.

[86] Dyk, *supra* note 1, at 77.

[87] *Id.*

[88] *See, e.g.*, Timothy B. Lee, *How a Rogue Appeals Court Wrecked the Patent System*, ARS TECHNICA (Sept. 30, 2012), http://arstechnica.com/tech-policy/2012/09/how-a-rogue-appeals-court-wrecked-thepatent-system/.

[89] Dyk, *supra* note 1, at 72 tbl. 2; *see also id.* at 71–72 ("Although one study of [October Term] 1999 to [October Term] 2008 calculated the median reversal rate for the circuits at around 68% and [the Federal Circuit's] reversal rate at 83%, this rate has declined in recent years. Over the last ten terms, our reversal rate has averaged around 70%, just slightly above the circuit median of 66.7%.").

between the Supreme Court and [the Federal Circuit] by the bar and by the academy" appears to exist, with some commentators questioning whether "the Supreme Court understands patent law well enough to make the governing rules," and others criticizing the Federal Circuit as "having a parochial attitude or a we know best attitude toward patent law."[90]

With respect to its patent docket, the Federal Circuit's appeals originate from three main sources: the federal district courts, the PTO, and the U.S. International Trade Commission.[91] Since the enactment of the AIA in 2011, however, there has been "substantial growth" in appeals coming from PTO proceedings: "In 2000, cases from the [PTO] made up only 4% of [the Federal Circuit's] docket while in 2016 they were 33%."[92] This trend demonstrates the significance of the PTO's administrative proceedings to the country's patent system.[93]

As noted, the Supreme Court has taken an increasing number of cases involving patent law and other areas of intellectual property over the last decade,[94] perhaps indicating the Court's heightened interest in patent law or recognition of its increased prominence in society as a whole.[95] Ten years ago, Judge Dyk predicted that the Supreme Court would continue its trend of hearing more cases from the Federal Circuit involving substantive patent law,[96] a prediction that is proving to hold true. Indeed, based on annual statistics on the Supreme Court published by the *Harvard Law Review*, from the October 2006 Term through the October 2015 Term "the Supreme Court has taken an average of four [Federal Circuit] cases each term, representing 5.4% of the Court's merits cases. A large proportion of those cases have involved substantive patent law or related procedural issues."[97] Because of this increase, one commentator has stated: "No longer is the Federal Circuit 'the de facto Supreme Court of patents.'"[98]

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[90] *Id.* at 80 ("As two commentators have uncharitably asked: 'Is the Supreme Court too unsophisticated in patent law to appreciate the wise insights of expert Federal Circuit judges, or are those Federal Circuit judges too narrowly focused on patent law to appreciate the broader rules of jurisprudence, procedure, and statutory interpretation?'" (quoting Jeff Bleich & Josh Patashnik, *The Federal Circuit Under Fire*, S.F. ATT'Y (Fall 2014), at 40, 41–42)).

[91] Dyk, *supra* note 1, at 77.

[92] *Id.* ("The proportion of patent cases coming from the district courts has not increased during my time on the court. Rather, the most substantial growth is in cases coming from the Patent Office.... Indeed, as some predicted, appeals from the Patent Office have overtaken those from the district courts.").

[93] *See* discussion *supra* in *Administrative Proceedings Before the PTO*.

[94] For a comprehensive list of Supreme Court cases involving patent law, see Lisa Larrimore Ouellette, *Supreme Court Patent Cases*, WRITTEN DESCRIPTION, https://writtendescription.blogspot.com/p/patents-scotus.html.

[95] *See* Robert M. Masters et al., *Intellectual Property Outlook: Cases and Trends to Follow in 2017*, 29 INTELL. PROP. & TECH. L.J. 3 (Apr. 2017) ("Over the past several years, the U.S. Supreme Court has become increasingly involved in the area of intellectual property law."); O'Malley, *supra* note 7, at 11 ("[T]he Supreme Court has shown a heightened level of interest in what this court does in the patent arena, and in whether we are doing it correctly.").

[96] Dyk, *supra* note 1, at 67.

[97] *Id.* at 67–68 ("In absolute terms, the Supreme Court has taken comparatively more cases from the Second, Fifth, Sixth, Ninth and Eleventh Circuits, and comparatively fewer from the First, Third, Seventh, Eighth, Tenth, and, surprisingly, District of Columbia Circuits."); *see also* O'Malley, *supra* note 7, at 9–10 ("Recent years have seen an unprecedented willingness by the Supreme Court to wade into patent actions within the Federal Circuit's jurisdiction. In the first decade of the circuit's existence, the Supreme Court took eighteen cases arising out of the Federal Circuit, only five of which were patent cases. While the number of patent cases going to the Supreme Court increased slightly in later decades, in the first twenty-eight years of the Federal Circuit's existence, the Supreme Court granted certiorari in fifty-one Federal Circuit cases, only twenty-two of which were patent cases. Between 2010 and today, however, the Supreme Court has taken twenty-two cases from Federal Circuit judgments, seventeen of which are patent cases."); Gugliuzza, *supra* note 9, at 332 ("[T]he Supreme Court's large docket of patent cases is unlikely to shrink soon. The Court has considered six patent cases in the 2016 Term, [which] ... build on three patent law decisions in the 2015 Term, three more in the 2014 Term, and six in the 2013 Term.").

[98] Gugliuzza, *supra* note 9, at 330 (quoting Mark D. Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001

While the High Court is playing a larger role in the development of patent law by issuing an increased number of patent law opinions, the nature and extent of the Court's influence on patent law is the subject of some debate.[99] Indeed, while Judge Dyk has asserted that "[t]he Supreme Court's decisions have had a major impact on patent law [and] ... have involved important and foundational questions with enormous impacts on patent litigation,"[100] others contend that "the sheer quantity of patent cases decided by the Supreme Court in recent years might make it seem as if the Court is serving as a percolating force in patent law by disrupting ossified doctrine and engaging in independent analyses of what the law should be.... But the key doctrines governing novelty, nonobviousness, and disclosure have remained relatively static."[101] Nonetheless, the increased number of Supreme Court opinions involving patent law has evinced several trends.[102]

One trend involves cases wherein the Court addresses a legal issue that is present in federal litigation generally, but appears to have been treated differently in the patent law context.[103] Examples include *eBay Inc. v. MercExchange, L.L.C.*, addressing the test for issuing injunctions;[104] *MedImmune, Inc. v. Genentech, Inc.*[105] and *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, addressing declaratory judgments;[106] and *Gunn v. Minton*, addressing subject matter jurisdiction.[107] A second trend involves an apparent effort on the part of the Court to

U. ILL. L. REV. 387, 387 (2001)).

[99] *Compare* Dyk, *supra* note 1, at 71 ("I continue to believe that Supreme Court review of our patent cases has been critical to the development of patent law and likewise beneficial to our court. 'The Supreme Court necessarily plays a critical role in reinterpreting, or even overruling, earlier Supreme Court decisions and in altering our jurisprudence to keep up with the demands of a changing world.'" (citation omitted)), *with* Donald R. Dunner, *Response to Judge Timothy B. Dyk*, 16 CHI.-KENT J. INTELL. PROP. 326, 326 (2017), *available at* http://scholarship.kentlaw.iit.edu/ckjip/vol16/iss2/4 ("Far from being beneficial to the Federal Circuit, the Supreme Court's review of Federal Circuit patent decisions has been detrimental to the performance of the Federal Circuit's mission: it has created uncertainty and a lack of predictability in corporate boardrooms, the very conditions that led to the Federal Circuit's formation."), *and* Gugliuzza, *supra* note 9, at 331 (suggesting "that the Supreme Court's effect on patent law has actually been more limited, for two reasons in particular. First, the Supreme Court's recent decisions, though substantial in number, have rarely involved the fundamental legal doctrines that directly ensure the inventiveness of patents and regulate their scope. Second, the Supreme Court's minimalist approach to opinion writing in patent cases frequently enables the Federal Circuit to ignore the Court's changes to governing doctrine.").

[100] Dyk, *supra* note 1, at 72–73.

[101] Dunner, *supra* note 99, at 347; *see also* Gugliuzza, *supra* note 9, at 338 ("[T]he Court ... has actually issued few opinions involving the truly 'foundational' provisions of the Patent Act—most notably, the requirements of patentability.... Though the Court has decided a remarkable thirty-three patent cases since 2006, it has decided precisely zero cases involving the novelty requirement of § 102. The Court has decided one case involving the disclosure requirements of § 112 [(Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014)].... The Court has also decided only one case involving the nonobviousness requirement of § 103 [(KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417–22 (2007))].").

[102] Under one formulation, the Supreme Court's recent patent law opinions can be divided into three groups: (1) cases involving a "transsubstantive" issue, or an issue that arises in all types of federal litigation, not just patent cases, such as issues of jurisdiction, procedure, and remedies; (2) cases presenting an opportunity to harmonize patent law with other areas of law, such as copyright law; and (3) cases involving statutory interpretation of the Patent Act. Gugliuzza, *supra* note 9, at 334–35.

[103] *Id.*

[104] 547 U.S. 388, 390 (2006). *See also* Dyk, *supra* note 1, at 76 ("[I]n *eBay* the Court sought to make sure that the standard for injunctive relief in the patent area is the same as for other federal causes of action.").

[105] 549 U.S. 118, 145 (2007).

[106] 134 S. Ct. 843, 852 (2013).

[107] 133 S. Ct. 1059, 1064 (2013). *See also* Dyk, *supra* note 1, at 76–77 ("[I]n *Medtronic* and *Medimmune* the Court clarified the constitutional and procedural dimensions to the Declaratory Judgment Act in the context of patent litigation.").

harmonize patent law with other areas of federal law, such as copyright.[108] Examples include *Global-Tech Appliances, Inc. v. SEB S.A.*, where the Court relied on the doctrine of willful blindness from criminal law to articulate the mental state requirement for induced patent infringement;[109] *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, wherein the Court relied on case law interpreting the fee-shifting provision of the Copyright Act to determine the appropriate standard for awarding attorney fees under the Patent Act;[110] and *Commil USA, LLC v. Cisco Sys., Inc.*, which drew upon knowledge requirements for civil and criminal liability to determine if liability for induced infringement is possible in the absence of actual knowledge.[111] As shall be seen, further examples of the trends are evident in some of the Court's opinions issued during its October 2016 Term, as discussed below.

Patent Cases of the Supreme Court's October 2016 Term

Cases Involving Procedural Issues

The Supreme Court issued two opinions involving procedural issues during its October 2016 Term that will affect *when* and *where* patent cases will be filed. Notably, in *TC Heartland LLC v. Kraft Foods Group Brands LLC*, the Court overruled long-standing Federal Circuit precedent with regard to venue rules in patent cases, holding "that a domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute."[112] And in *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, the Court ruled that the equitable doctrine of laches, which protects against unreasonable, prejudicial delay in commencing suit, is not available in a patent infringement action filed within the Patent Act's statute of limitations.[113]

TC Heartland v. Kraft Foods Group Brands

TC Heartland centered on the meaning of the patent venue statute, 28 U.S.C. § 1400(b), which provides that "[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business."[114] Congress has amended the *general* venue statute twice, but has not amended the *patent-specific* statute,[115] since the Court issued its 1957 opinion

[108] Gugliuzza, *supra* note 9, at 336 ("The Supreme Court has also repeatedly harmonized (or considered harmonizing) patent law with other substantive areas of federal law, including other fields of intellectual property law."); *see also* Dyk, *supra* note 1, at 76 ("What is interesting ... is that a significant proportion of the Supreme Court's cases from [the Federal Circuit] involve reconciling [the Federal Circuit's] jurisprudence with jurisprudence in other areas. In other words, the Supreme Court thinks that part of its task is to bring to bear its generalist perspective on [the Federal Circuit's] specialty areas.").

[109] 563 U.S. 754 (2011).

[110] 134 S. Ct. 1749 (2014).

[111] 135 S. Ct. 1920 (2015). *See also* Dyk, *supra* note 1, at 76 ("In *Commil* the Court brought its understanding of civil and criminal liability to bear on the issue of induced infringement where an actor lacks actual knowledge that the conduct violates the law.").

[112] 137 S. Ct. 1514, 1517 (2017).

[113] 137 S. Ct. 954 (2017).

[114] 28 U.S.C. § 1400(b).

[115] *TC Heartland*, 137 S. Ct. at 1517.

in *Fourco Glass Co. v. Transmirra Products Corp.*, which held that the patent-specific venue statute "is the sole and exclusive provision controlling venue in patent infringement actions, and ... is not to be supplemented by ... [the general venue statute, 28 U.S.C.] § 1391(c)." Nevertheless, after Congress amended the *general* venue statute in 1988 (but not the *patent-specific* statute), the Federal Circuit held in 1990 that this change also altered the patent-specific statute by reference.[116]

Specifically, under the 1988 amendments, the general venue statute provided that, "[f]or purposes of venue *under this chapter*, a defendant that is a corporation shall be deemed to reside in any judicial district in which it is *subject to personal jurisdiction* at the time the action is commenced."[117] In *VE Holding Corp. v. Johnson Gas Appliance Co.*, the Federal Circuit held that through this amendment of the general venue statute, Congress also changed the meaning of "resides" in the patent-specific venue statute.[118] Accordingly, in the time since *VE Holding* was issued, the Federal Circuit has followed the rule that venue in patent cases is proper anywhere a defendant is subject to personal jurisdiction.[119]

In 2011, Congress enacted the current version of the *general* venue statute, again leaving the *patent-specific* statute unaltered. Similar to the 1988 version, the present general venue statute provides: "Except as otherwise provided by law" and "[*f*]*or all venue purposes*," a corporation "shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court's *personal jurisdiction* with respect to the civil action in question."[120] The Federal Circuit considered this amendment in its opinion in *TC Heartland*, and reaffirmed its holding in *VE Holding*, "reasoning that the 2011 amendments provided no basis to reconsider its prior decision."[121]

In 2014, Kraft Foods, a corporation organized under Delaware law with its principal place of business in Illinois, sued TC Heartland, a company organized under Indiana law and headquartered in Indiana, for patent infringement in the federal district court for the District of Delaware.[122] Although TC Heartland was not registered to conduct business in Delaware, and had no meaningful presence there, it had shipped a small amount of the allegedly infringing products into Delaware.[123] Relying on *VE Holding Corp.*, the district court in Delaware dismissed TC Heartland's motion to dismiss the case or transfer venue to the district court for the Southern

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[116] *Id.* at 1519.

[117] 28 U.S.C. § 1391(c) (1988) (emphases added).

[118] 917 F.2d 1574, 1578 (Fed. Cir. 1990) (emphases added) ("The phrase 'this chapter' refers to chapter 87 of title 28, which encompasses §§ 1391–1412, and thus includes § 1400(b). On its face, § 1391(c) clearly applies to § 1400(b), and thus redefines the meaning of the term 'resides' in that section.").

[119] Ana Santos Rutschman, *Patent Venue Exceptionalism after* TC Heartland v. Kraft, 25 U. MIAMI BUS. L. REV. 29, 30 (2017), *available at* http://repository.law.miami.edu/umblr/vol25/iss2/4 ("For the past quarter of a century, the Federal Circuit has interpreted the patent venue statute permissively, enabling patentees to bring a lawsuit against a corporation in any district where personal jurisdiction arises. In the case of national companies like Heartland, this permissive approach allows patent infringement lawsuits to be brought anywhere in the United States where a modicum of sales may occur." (footnotes omitted)).

[120] 28 U.S.C. § 1391(a), (c) (emphases added).

[121] *TC Heartland*, 137 S. Ct. at 1520.

[122] *Id.* at 1517.

[123] *Id. See generally* Rutschman, *supra* note 119, at 30 ("[I]n 2013, some of Heartland's accused products (representing approximately 2% of Heartland's annual sales) were drop-shipped to locations in Delaware at the request of an Arkansas-based customer. The court deemed this link sufficient to trigger personal jurisdiction in the patent lawsuit brought by Kraft.").

District of Indiana, and the Federal Circuit subsequently denied TC Heartland's petition for a writ of mandamus on the same grounds.[124]

In a unanimous opinion for the Court, Justice Clarence Thomas reversed the Federal Circuit based on *Fourco*.[125] In reversing, the Supreme Court stated: "In *Fourco,* this Court definitively and unambiguously held that the word 'reside[nce]' in § 1400(b) has a particular meaning as applied to domestic corporations: It refers only to the State of incorporation. Congress has not amended § 1400(b) since *Fourco,* and neither party asks us to reconsider our holding in that case."[126] Thus, the Court "conclude[d] that the amendments to § 1391 [(i.e., the general venue statute)] did not modify the meaning of § 1400(b) [(i.e., the patent-specific venue statute)] as interpreted by *Fourco*. [The Court] therefore h[e]ld that a domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute."[127]

The practical effects of the Federal Circuit's ruling in *VE Holdings* were dramatic. In fact, although there are ninety-four federal district courts in the United States, a single district court, that of the Eastern District of Texas, received almost half (44%) of all patent cases filed in 2015.[128] By way of comparison, the District of Delaware had the second largest number of patent cases at 9%, followed by the Central and North Districts of California with 5% and 4%, respectively.[129] In addition, one judge in the Eastern District of Texas handled two-thirds of the district's patent cases, meaning a single judge was assigned to nearly one-third of all the country's patent cases.[130] Commentators have suggested that the popularity of the Eastern District of Texas as a venue for patent cases post-*VE Holdings*[131] cannot be attributed to "geographical clustering of patent-intensive industries, as major technology hubs are located elsewhere," but is instead explained by "the patentee-friendly reputation of the district, attracting litigation through

[124] *TC Heartland*, 137 S. Ct. at 1517.

[125] 353 U.S. 222, 229 (1957). A patent-specific venue statute was first enacted in 1897, Act of Mar. 3, 1897, ch. 395, 29 Stat. 695, to resolve conflicts among various court opinions as to whether or not the general venue statute applied to patent cases. *See TC Heartland*, 137 S. Ct. at 1518.

[126] *Id.* (footnote omitted).

[127] *Id.* at 1517.

[128] Rutschman, *supra* note 119, at 35; *see also* Letter from Forty-Five U.S. Law School Professors, to Senators Charles Grassley and Patrick Leahy, Chairman and Ranking Member, respectively, of the Senate Committee on the Judiciary, and Representatives Bob Goodlatte and John Conyers, Chairman and Ranking Member, respectively, of the House Committee on the Judiciary, (July 12, 2016), *available at* https://drive.google.com/file/d/0B4BdaKgM6bo7cUt1YXdfSFBSOFQyaXJvRnVBS3pBQXZMLURR/view [hereinafter *Letter to Congress*] ("Of the 5,819 patent cases filed in 2015, nearly half—2,541 cases—were filed in the Eastern District of Texas.... And the Eastern District of Texas's percentage of patent cases has been steadily increasing over the last several years, rising from 11% in 2008 to 44% in 2015. By comparison, the Northern District of California, home of Silicon Valley, saw only 228 patent cases filed in 2015."); Crouch, Dennis, *Law Professors Call for Patent Venue Reform*, PATENTLYO.COM (July 13, 2016), https://patentlyo.com/patent/2016/07/professors-patent-reform.html (reprinting letter to Congress).

[129] Rutschman, *supra* note 119, at 35.

[130] *Letter to Congress*, *supra* note 128, at 1 ("A single judge in the Eastern District of Texas had 1,686 patent cases filed assigned to his docket in 2015—in other words, a single judge handled two-thirds of the patent cases in that district, and nearly one-third of all patent cases nationwide. If all of those cases were to go to trial, that single judge would have to complete 4 to 5 trials every day of the year (including weekends)—not counting any time for motions or other hearings." (footnotes omitted)).

[131] After the Federal Circuit's opinion was issued in *VE Holding*, "the Eastern District of Texas went from a total of 14 patent cases in 1999 to nearly 200 patent cases a year by the mid-2000s; in 2012 that number skyrocketed to 1,247, while in 2015 it more than doubled to a grand total of 2,540. Between 2007 and the first half of 2016, the Eastern District of Texas attracted 20% of national patent litigation, followed by Delaware (12%) and the Central District of California (8%)." Rutschman, *supra* note 119, at 35 (footnotes omitted).

favorable procedural and administrative practices in patent cases."[132] Perhaps unsurprisingly, calls for venue reform in patent cases came from many corners,[133] particularly in light of the attention the issue received in national media reporting, such as stories describing "the empty Texas offices rented by patentees and the skating rink sponsored by Samsung just outside the courthouse to curry favor with local juries."[134] The issue has also been the subject of legislative proposals, as recently as last year.[135] The Supreme Court's decision in *TC Heartland*, however, arguably dissipates many of these concerns.

As to the immediate impact of the *TC Heartland* decision, since it was issued on May 22, 2017, patent complaints filed in July 2017 in the Eastern District of Texas decreased 43% compared to June 2017, which is a decrease of 83% compared to July 2016.[136] And, conversely, the District Court for Delaware received the greatest number of patent complaints for two months in a row after the opinion was issued, twice as many when compared to the same time year ago.[137] Similarly, patent filings in the District Court for Central California increased by more than a third after the opinion was issued.[138] The long-term effects of *TC Heartland*, however, remain to be seen.[139]

Of note to Congress, in addition to a potential long-term geographic redistribution of patent cases among the federal district courts,[140] commentators have also suggested that *TC Heartland* may

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[132] *See id.* at 35–37 (noting, among the reasons for the popularity of the Eastern District of Texas, a "hostility of summary judgment," a "historical[ ] resist[ance to] the transfer of patent cases," the possibility of learning the identity of the judge assigned to a case in advance, and the District's reputation for swiftness); *see also Letter to Congress*, *supra* note 128, at 2 ("One reason for the disproportionate number of patent filings in the Eastern District of Texas is that the district employs procedural rules and practices that attract plaintiffs, including by delaying or denying the ability of defendants to obtain summary judgment to terminate meritless cases early. For example, the district requires parties seeking summary judgment in patent cases to first seek permission before filing any summary judgment motion, the effect of which is to delay and deter early resolution of cases." (footnotes omitted)).

[133] *See, e.g.*, *Letter to Congress*, *supra* note 128, at 1 ("Changes to the venue rules are necessary and urgent to address the significant problem of forum shopping in patent litigation cases."); Colleen V. Chien & Michael Risch, *A Patent Reform We Can All Agree On*, WASH. POST (Nov. 20, 2015), https://www.washingtonpost.com/news/in-theory/wp/2015/11/20/why-do-patent-lawyers-like-to-file-in-texas/?utm_term=.f7e93f02e875 ("The staggering concentration of patent cases in just a few federal district courts is bad for the patent system. We believe that changing where patent lawsuits can be filed will solve many of the problems in the debate.").

[134] Chien & Risch, *supra* note 133; *see also* Rutschman, *supra* note 119, at 43 n.101 (describing as one of "the most outrageous side effects of the permissive approach to venue" "the construction of an ice rink by Samsung in front of the Marshall, Texas courthouse, where Samsung has repeatedly been sued for patent infringement, in attempt to maintain a positive image of the company among potential jurors").

[135] *See, e.g.*, Venue Equity and Non-Uniformity Elimination Act of 2016, S. 2733, 114th Cong. (2016).

[136] Malathi Nayak, *East Texas Court Patent Complaints Continue to Tumble*, BLOOMBERG BNA (Aug. 7, 2017), https://www.bna.com/east-texas-court-n73014462877/ ("[T]he Eastern District of Texas in July continued to slip from its longstanding place as the top venue for patent infringement complaints, less than two months after a U.S. Supreme Court ruling limiting where patent owners can file.").

[137] *Id.* ("[T]he District of Delaware held its rank as top venue for patent complaints for a second month in a row, receiving 68 complaints, more than double a year ago but up by only two from June.").

[138] *Id.* ("[T]he Central District of California saw patent complaints increase by more than a third to 46 in July, compared with June.").

[139] For instance, the Eastern District of Texas saw an increase in patent filings in August 2017. *See* Malathi Nayak, *Eastern Texas Court Sees August Bump in Patent Complaints*, BLOOMBERG BNA (Sept. 6, 2017), https://www.bna.com/eastern-texas-court-n73014464244/ ("A Texas federal district court with a patentee-friendly reputation is no longer the busiest patent court in the U.S., but saw a rise in patent infringement filings in August, including claims against Target Corp., Apple Inc., and Samsung Electronics Co. Ltd., Bloomberg Law data show.").

[140] *Id.* ("Delaware was widely expected by attorneys and academics to see a jump in filings [after *TC Heartland*] because many companies incorporate there.").

curb cases filed by non-practicing entities, better known as "patent trolls."[141] Non-practicing entities are "patent owners who do not actually practice the invention that is the subject of the patent.... Trolls are generally considered entities that purchase patents for the purpose of generating capital by enforcing them."[142] Of the cases filed in the Eastern District of Texas in 2015 (which as noted constituted 44% of the country's patent filings), 95% were filed by non-practicing entities.[143] Thus, the unavailability of that venue for the many patent cases that are filed against corporations that are not incorporated in that forum may disincentivize the filing of patent cases by non-practicing entities.[144]

SCA Hygiene Products Aktiebolag v. First Quality Baby Products

Another opinion involving a procedural issue, but arguably with potentially fewer ramifications, is the Court's opinion in *SCA Hygiene Products Aktiebolag v. First Quality Baby Products*, wherein the Court addressed "the relationship between the equitable defense of laches and claims for damages that are brought within the time allowed by a statute of limitations."[145] This was the subject of the Court's opinion three years earlier, in the context of the Copyright Act, in *Petrella v. Metro-Goldwyn-Mayer, Inc.*, wherein the Court concluded "in face of a statute of limitations enacted by Congress, laches cannot be invoked to bar legal relief."[146] In *SCA Hygiene*, the Court held that "*Petrella*'s reasoning applies to a similar [statute of limitations] provision of the Patent Act," 35 U.S.C. § 286, and therefore "[l]aches cannot be interposed as a defense against damages where the infringement occurred within the period prescribed by § 286."[147] Thus, this opinion can be viewed as an example of one in which the Court harmonizes patent law with other areas of federal law, as discussed above.[148]

The underlying suit began in October 2003 when SCA, a manufacturer of adult incontinence products, sent a letter to First Quality alleging that the company was making and selling

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[141] *See, e.g.*, Chris Welch, *The US Supreme Court Just Made Life Much Harder for Patent Trolls*, THE VERGE (May 22, 2017), https://www.theverge.com/2017/5/22/15676206/supreme-court-patent-venue-ruling; Daniel Nazer, *Supreme Court Ends Texas' Grip on Patent Cases*, ELECTRONIC FRONTIER FOUNDATION (May 22, 2017), https://www.eff.org/deeplinks/2017/05/supreme-court-ends-texas-grip-patent-cases.

[142] O'Malley, *supra* note 7, at 5 ("A recent Government Accountability Office study estimates that about twenty percent of patent cases are prosecuted by non-practicing entities, though many argue that this estimate is low." (footnotes omitted)).

[143] *Letter to Congress*, *supra* note 128, at 1 (footnotes omitted).

[144] *See* Welch, *supra* note 141 ("The Supreme Court has dealt a significant blow to 'patent trolls' that often sue and squeeze a quick payday out of major technology companies using patents that they've bought up for that exact purpose. Today, the court unanimously ruled that a defendant should only face patent litigation in the state where it's incorporated. For Apple, that would be California. For a ton of other US companies, it's the state of Delaware."); Nazer, *supra* note 141 ("Today the Supreme Court issued a decision that will have a massive impact on patent troll litigation. In *TC Heartland v. Kraft Foods*, the court ruled that patent owners can sue corporate defendants only in districts where the defendant is incorporated or has committed acts of infringement and has a regular and established place of business. This means that patent trolls can no longer drag companies to distant and inconvenient forums that favor patent owners but have little connection to the dispute. Most significantly, it will be much harder for trolls to sue in the Eastern District of Texas.").

[145] 137 S. Ct. 954, 959 (2017). "[T]he equitable defense of laches" is available in light of an "unreasonable, prejudicial delay in commencing suit." Petrella v. Metro-Goldwyn-Mayer, Inc., 134 S. Ct. 1962, 1967 (2014).

[146] *Petrella*, 134 S. Ct. at 1974; *see also* Gugliuzza, *supra* note 9, at 336 ("In *SCA Hygiene*, the Court held that an infringer may not invoke the equitable doctrine of laches as a defense to a claim of patent infringement, just three years after holding that laches is not a defense to a claim for damages for copyright infringement.").

[147] *SCA Hygiene*, 137 S. Ct. at 959, 967.

[148] *See* discussion *supra* in *Proceedings Before the Federal Courts*.

infringing products.[149] In response, First Quality informed SCA that one of First Quality's patents actually antedated SCA's patent, and therefore SCA's own patent was invalid.[150] No further communication between the companies occurred until August 2010, when SCA filed a patent infringement action again First Quality.[151] In the intervening period, SCA had initiated a reexamination proceeding before the PTO,[152] and obtained a certificate confirming the validity of SCA's patent in light of First Quality's patent.[153] First Quality moved to dismiss SCA's infringement action based on laches and equitable estoppel. In an en banc opinion, the Federal Circuit held that laches can defeat an infringement claim for damages even if it was filed within the Patent Act's six-year statute of limitations.[154] The Supreme Court reversed based on its opinion in *Petrella*.

Of possible interest to Congress, the Court in *SCA Hygiene* emphasized that:

> *Petrella*'s holding rested on ... separation-of-powers principles.... When Congress enacts a statute of limitations, it speaks directly to the issue of timeliness and provides a rule for determining whether a claim is timely enough to permit relief. The enactment of a statute of limitations necessarily reflects a congressional decision that the timeliness of covered claims is better judged on the basis of a generally hard and fast rule rather than the sort of case-specific judicial determination that occurs when a laches defense is asserted. Therefore, applying laches within a limitations period specified by Congress would give judges a "legislation-overriding" role that is beyond the Judiciary's power. As we stressed in *Petrella*, "courts are not at liberty to jettison Congress' judgment on the timeliness of suit."[155]

Accordingly, in *SCA Hygiene* the High Court demonstrated that its prohibition on the use of laches as an equitable defense in cases claiming damages extends beyond the copyright context of *Petrella*, and may extend to arguably all statute of limitations enacted by Congress. Thus, the unavailability of laches is a consideration when such statutes are drafted.

One potential practical consequence of the Court's *SCA Hygiene* opinion, as described in Justice Stephen Breyer's dissenting opinion and by at least one commentator,[156] is that patent holders may now wait until close to the expiration of the six-year limitations period to file infringement cases so that damages will have the maximum amount of time to accrue.[157] As Justice Breyer

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[149] *SCA Hygiene*, 137 S. Ct. at 959.

[150] *Id.*

[151] *Id.*

[152] *See* discussion *supra* in *Administrative Proceedings Before the PTO*.

[153] *SCA Hygiene*, 137 S. Ct. at 959.

[154] SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 807 F.3d 1311, 1328 (Fed. Cir. 2015) (reasoning that in the Patent Act's statute of limitations, "Congress codified a laches defense that barred recovery of legal remedies.").

[155] *SCA Hygiene*, 137 S. Ct. at 960 (quoting Petrella v. Metro-Goldwyn-Mayer, Inc., 134 S. Ct. 1962, 1967 (2014)).

[156] *Id.* at 967 (Breyer, J., dissenting) (arguing that "for more than a century courts with virtual unanimity have applied laches in patent damages cases. Congress, when it wrote the 1952 statute, was aware of and intended to codify that judicial practice"); *see also* Gene Quinn, *Supreme Court Says Laches is No Defense to Patent Infringement*, IP WATCHDOG (Mar. 22, 2017), http://www.ipwatchdog.com/2017/03/22/supreme-court-says-laches-no-defense-patent-infringement/id=79750/ ("[W]ithout a laches defense possible, a patent owner could lie in wait for infringement to become widespread and then sue for infringement seeking only the previous six-years worth of damages.").

[157] *See* Quinn, *supra* note 156 ("[I]n the wake of the Supreme Court's decision in *SCA Hygiene*, patent owners would do well to consider forgoing patent enforcement. Instead, allow infringement to accrue and then sue for infringement in several years when the law may be quite a bit more favorable. After all, patents can last for 20 years, the statute of limitations is six-years, and without a laches defense available to infringers you will be able to seek damages going

observed, in the wake of *SCA Hygiene*, "a patentee has considerable incentive to delay suit until the costs of switching—and accordingly the settlement value of a claim—are high. The practical consequences of such delay can be significant, as the facts of this case illustrate: First Quality invested hundreds of millions of dollars in its allegedly infringing technologies during the years that SCA waited to bring its suit."[158] And, unlike the Patent Act, Justice Breyer points out that the Copyright Act "has express provisions that mitigate the unfairness of a copyright holder waiting for decades to bring his lawsuit."[159] This, according to Justice Breyer, is a difference between the patent and copyright regimes that should have prevented the majority from applying *Petrella* in the patent law arena. The extent to which this tactic will be used in future patent litigation of course remains to be seen.

Cases Involving Multicomponent Products

In another pair of cases heard during the Supreme Court's October 2016 Term, the Supreme Court dealt with issues related to patents on multicomponent inventions—one in the context of determining infringement[160] and another in the context of calculating damages.[161]

Life Technologies v. Promega

Section 271(f)(1) of the Patent Act provides that anyone who supplies "in or from the United States all or a *substantial portion of the components* of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer."[162] In *Life Technologies v. Promega*, the Supreme Court addressed "whether the supply of a single component of a multicomponent invention is an infringing act under [this provision]."[163] The Court held that it does not, stating "a single component does not constitute a substantial portion of the components that can give rise to liability under § 271(f)(1)."[164]

Life Technologies involved a license for a patent on a toolkit for genetic testing.[165] The toolkit covered by the patent contained five components, one of which was the enzyme *Taq* polymerase.[166] Promega was the exclusive licensee of the patent and sublicensed it to Life Technologies, a manufacturer of genetic testing kits.[167] Life Technologies manufactured all components of its toolkits in the United Kingdom, except for the *Taq* polymerase, which it made

back six years from whenever you choose to sue.").

[158] *SCA Hygiene*, 137 S. Ct. at 972 (Breyer, J., dissenting).

[159] *Id.* at 971–72 ("A copyright holder who tries to lie in wait to see if a defendant's investment will prove successful will discover that the Copyright Act allows that defendant to 'prove and offset against ... profits 'deductible expenses' incurred in generating those profits.'" (quoting 17 U.S.C. § 504(b))).

[160] Life Techs. Corp. v. Promega Corp., 137 S. Ct. 734 (2017).

[161] Samsung Elecs. Co. v. Apple Inc., 137 S. Ct. 429 (2016).

[162] 35 U.S.C. § 271(f)(1) (emphasis added).

[163] 137 S. Ct. 734, 739 (2017).

[164] *Id.*

[165] *Id.* at 738.

[166] *Id.*

[167] *Id.*

in the United States.[168] The company then shipped the *Taq* polymerase to its United Kingdom facility, where it was combined with the other four components of the kit.[169] Four years into this agreement, Promega sued Life Technologies on the grounds that it infringed the patent by selling the toolkits outside of the allowable fields of use in the license, which was limited to clinical and research markets.[170] Because Life Technologies supplied the *Taq* polymerase from the United States to its United Kingdom manufacturing facilities, Promega alleged liability under § 271(f)(1).[171]

On appeal to the Federal Circuit, the court held that "there are circumstances in which a party may be liable under § 271(f)(1) for supplying or causing to be supplied a single component for combination outside the United States."[172] Based on the facts of this case, the court concluded "that substantial evidence supports the jury's verdict that LifeTech is liable for infringement under § 271(f)(1) for shipping the *Taq* polymerase component of its accused genetic testing kits to its United Kingdom facility."[173] The Supreme Court disagreed.

The High Court started with what it considered a "threshold determination" as to "whether § 271(f)(2)'s requirement of 'a substantial portion' of the components of a patented invention refers to a *quantitative* or *qualitative* measurement."[174] Based on the text of the statute, the Court concluded that "[t]he context in which 'substantial' appears in the statute ... points to a quantitative meaning here."[175] Next, the Court addressed "whether, as a matter of law, a single component can ever constitute a 'substantial portion' so as to trigger liability under § 271(f)(1)," and concluded "[t]he answer is no."[176] Therefore, the Court held "that § 271(f)(1) does not cover the supply of a single component of a multicomponent invention."[177]

This case may appear to be limited to its facts, but arguably has consequences in a marketplace characterized by global supply chains, as well as for the presumption against extraterritoriality, under which this country's patent laws are said to only have force on U.S. soil.[178] While the opinion does not discuss the presumption, it begins with the assertion that "[t]his case concerns the intersection of international supply chains and federal patent law."[179] One observer has noted that, despite not providing guidance on the presumption against extraterritoriality, to some extent

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[168] *Id.*

[169] *Id.*

[170] *Id.*

[171] *Id.*

[172] Promega Corp. v. Life Techs. Corp., 773 F.3d 1338, 1353 (Fed. Cir. 2014), *rev'd and remanded*, 137 S. Ct. 734 (2017).

[173] *Id.*

[174] *Life Techs.*, 137 S. Ct. at 739 (emphases added).

[175] *Id.* at 740–41 ("[W]e conclude that a quantitative interpretation hews most closely to the text of the statute and provides an administrable construction.").

[176] *Id.* at 741.

[177] *Id.* at 743.

[178] *See* Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 454–55 (2007) (defining the "presumption against extraterritoriality" as "[t]he presumption that United States law governs domestically but does not rule the world," which "applies with particular force in patent law"); *see* Tim Holbrook, *Life Technologies Corp. v. Promega Corp. and the Absent Presumption Against Extraterritoriality*, PATENTLY-O (Feb. 26, 2017), https://patentlyo.com/patent/2017/02/technologies-presumption-extraterritoriality.html (noting that "most viewed [*Life Technologies*] as one of a series of cases in which the Court was elaborating on the presumption against extraterritoriality. At oral argument, the questions from the justices suggested that likely was the case as well. The term was used over twelve times in the argument....").

[179] *Life Techs.*, 137 S. Ct. at 737.

the opinion delineates aspects of "the risk that some parts of the [global supply] chain could be exposed to patent infringement liability."[180] As another commentator put it, the Court's holding "that a single component never qualifies as a substantial portion of the components—tends to curb the extraterritorial effects of Section 271(f), and that result is sensible given that the baseline rule of U.S. patent law is still a principle of territoriality."[181] Thus, this case is of particular interest to those who manufacture multicomponent products, such as smartphones—the subject of the Court's other case involving multicomponent products this term—outside of the United States.

Samsung Electronics v. Apple

In a second case involving multicomponent products—this time Apple's iPhone—the Supreme Court was again called upon to interpret the Patent Act, this time to determine:

> whether, in the case of a multicomponent product, the relevant "article of manufacture" must always be the end product sold to the consumer or whether it can also be a component of that product. Under the former interpretation, a patent holder will always be entitled to the infringer's total profit from the end product. Under the latter interpretation, a patent holder will sometimes be entitled to the infringer's total profit from a component of the end product.[182]

Under § 289 of the Patent Act, anyone who manufactures or sells "any article of manufacture to which [a patented] design or colorable imitation has been applied shall be liable to the owner to the extent of his total profit."[183] In *Samsung Electronics v. Apple*, the Federal Circuit identified Samsung's entire smartphone as the "article of manufacture" for purposes of calculating damages under § 289 because "[t]he innards of Samsung's smartphones were not sold separately from their shells as distinct articles of manufacture to ordinary purchasers."[184] The Supreme Court disagreed.

The underlying infringement case involved three Apple design patents[185] for its iPhone: "the D618,677 patent, covering a black rectangular front face with rounded corners, the D593,087

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[180] Holbrook, *supra* note 178.

[181] Duffy, John, *Opinion Analysis: A "Substantial Portion of the Components" Means "More than One Component,"* SCOTUSBLOG (Feb. 23, 2017), http://www.scotusblog.com/2017/02/opinion-analysis-substantial-portion-components-means-one-component/ ("[T]his relatively minor case offers lessons about important issues, including the effects of foreign activity on U.S. patent suits, the proper approach to statutory interpretation, and the continuing evolution of the Federal Circuit's relationship with the Supreme Court.").

[182] Samsung Elecs. Co. v. Apple Inc., 137 S. Ct. 429, 434 (2016).

[183] 35 U.S.C. § 289.

[184] Apple Inc. v. Samsung Elecs. Co., 786 F.3d 983, 1002 (Fed. Cir. 2015), *rev'd and remanded*, 137 S. Ct. 429 (2016).

[185] In addition to granting "utility patents" for machines, manufactures, compositions of matter and processes, 35 U.S.C. § 101, the Patent Act also extends patent protection to "new, original and ornamental design for an article of manufacture," so-called design patents, subject to some conditions, *id.* § 171(a). Such a patent is infringed "if, in the eye of an ordinary observer, giving such attention as a purchaser usually gives, two designs are substantially the same, if the resemblance is such as to deceive such an observer, inducing him to purchase one supposing it to be the other, the first one patented is infringed by the other." Gorham Mfg. Co. v. White, 81 U.S. 511, 528 (1871).

Interestingly, the issue of design patents was raised in another opinion issued by the Court during its October 2016 Term. *Star Athletica, L.L.C. v. Varsity Brands, Inc.* involved a copyright infringement challenge based on designs for cheerleading uniforms, and was decided based on copyright law. 137 S. Ct. 1002 (2017). With regard to design patents, however, the Court addressed the argument that "Congress intends to channel intellectual property claims for industrial design into design patents," and not copyright claims. *Id.* at 1015. Thus, it was argued, the Court should approach the copyright challenge "with a presumption against copyrightability." *Id.* In response, the Court explained that it has "long held that design patent and copyright are not mutually exclusive. Congress has provided for limited copyright

patent, covering a rectangular front face with rounded corners and a raised rim, and the D604,305 patent, covering a grid of 16 colorful icons on a black screen."[186] After Apple released the first generation of its iPhone in 2007, Samsung released a series of smartphones that resembled Apple's iPhone.[187] A jury found Samsung's smartphones infringed the design patents and awarded Apple $399 million in damages, Samsung's entire profit from sales of the infringing smartphones, which the Federal Circuit upheld.[188]

In reversing, the Supreme Court grounded its decision on its interpretation of the statutory term "article of manufacture," which it found to be "broad enough to encompass both a product sold to a consumer as well as a component of that product. A component of a product, no less than the product itself, is a thing made by hand or machine."[189] In doing so, the Court found the Federal Circuit's reading of "'article of manufacture' in § 289 to cover only an end product sold to a consumer gives too narrow a meaning to the phrase," but the Court remanded to the Federal Circuit to determine the relevant article of manufacture for the each of the design patents found to be infringed in this case.[190] Resolution of that issue is ongoing.[191]

While this case was limited to the issue of damages in the context of Apple's design patents, it is but one of many patent cases between Apple and Samsung related to their smartphones. In fact, on June 26, 2017, the Supreme Court invited the Solicitor General to file a brief "expressing the views of the United States" on Samsung's petition for certiorari to review the Federal Circuit's decision in another *Samsung Electronics v. Apple* case.[192] That case involves three Apple patents: one patent covering the iPhone's autocorrect function, one covering the iPhone's "slide-to-unlock" feature, and one covering the iPhone's "quick links" feature, which initiates certain actions when users click on certain data (e.g., starting an email message when a user clicks on an email address). In an en banc opinion, the Federal Circuit upheld a jury verdict that found Samsung infringed all three patents, thereby overturning a Federal Circuit panel decision that found the autocorrect and slide-to-unlock patents were invalid as obvious and the quick links patent was not infringed.[193] Should the Court grant certiorari in this case, it could have implications for substantive patent law, in particular the patentability requirement of nonobviousness.[194]

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protection for certain features of industrial design, and approaching the statute with presumptive hostility toward protection for industrial design would undermine Congress' choice." *Id.* (citations omitted)); *but see id.* at 1035 (Breyer, J., dissenting) ("Congress' decision not to grant full copyright protection to the fashion industry has not left the industry without protection. Patent design protection is available. A maker of clothing can obtain trademark protection under the Lanham Act for signature features of the clothing. And a designer who creates an original textile design can receive copyright protection for that pattern as placed, for example, on a bolt of cloth, or anything made with that cloth.... The fashion industry has thrived against this backdrop, and designers have contributed immeasurably to artistic and personal self-expression through clothing.").

[186] *Samsung*, 137 S. Ct. at 433.

[187] *Id.*

[188] *Id.* at 433–34.

[189] *Id.* at 435.

[190] *Id.*

[191] *See generally* Apple Inc. v. Samsung Elecs. Co., No. 11-CV-01846-LHK, 2017 WL 3232424 (N.D. Cal. July 28, 2017).

[192] Samsung Electronics Co. v. Apple Inc., No. 16-1102 (U.S.) (docketed Mar. 10, 2017).

[193] Samsung Electronics Co. v. Apple Inc., 839 F.3d 1034 (Fed. Cir. 2016) (en banc).

[194] *See* Derek Dahlgren & Spencer Johnson, *Obviousness May Soon Return to High Court*, LAW360 EXPERT ANALYSIS (June 16, 2017), https://www.law360.com/articles/935776/obviousness-may-soon-return-to-high-court.

Cases with Implications for the Health Care Industry

A final pair of patent cases decided by the Supreme Court during its October 2016 Term may have major implications for the pharmaceutical industry. According to the U.S. Department of Commerce, in 2015, pharmaceutical sales in the United States grossed $333 billion, comprising 1.9% of gross domestic product.[195] While the U.S. pharmaceutical industry stands as one of the largest sectors of the economy, it is also among the most research and development (R&D) intensive—the "industry generally allocates 15–20 percent of revenues to R&D activities and invests over $50 billion on R&D annually."[196] Furthermore, with only about a 10%[197] chance of succeeding, moving an investigative drug through the costly and time-consuming[198] Food and Drug Administration (FDA) approval process means the stakes for research-based pharmaceutical companies are high, necessitating a legal regime that encourages such companies to make the necessary investments to create new drug products.[199] At the same time, the high costs of R&D have, in turn, led to correspondingly high costs to consumers for pharmaceutical products, requiring laws that encourage competition among drug manufacturers to drive down drug costs. These conflicting interests—the interest in innovation and the interest in competition—lie at the heart of the law regulating pharmaceuticals.[200]

The Legal Landscape for Health Care Innovators

It is in this context that the Supreme Court issued two opinions this term at the intersection of patent and food and drug law, both of which raise issues of interest to Congress, as the Court gauges the proper balance Congress sought between innovation and competition in federal drug law. This section of the report will begin with a brief background on the legal landscape for health innovators, particularly, the patent regime and regulatory framework for medical products in the United States. Next, this section will cover the Supreme Court's decision in *Impression Products v. Lexmark*, a case centered on the patent exhaustion doctrine with implications across industries, particularly the pharmaceutical and medical device industries. Last, this section will cover the Supreme Court's decision in *Sandoz v. Amgen*, a case in which the Court interpreted certain statutory provisions in the Biologics Price Competition and Innovation Act (BPCIA),[201] with the potential to affect the speed at which competition emerges for biologic products.

As noted, the U.S. patent law regime working in tandem with other statutorily prescribed protections—in particular, those provided for under food and drug law—has established a legal

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[195] Int'l Trade Admin., 2016 Top Markets Report Pharmaceuticals: Overview and Key FINDINGS 3 (2016), http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf.

[196] *Id*.

[197] *See* BIOTECHNOLOGY INNOVATION ORG., CLINICAL DEVELOPMENT SUCCESS RATES 2006–2015 7 (2016) (concluding that "the overall likelihood of [drug] approval from Phase 1 [clinical trial] for all developmental candidates was 9.6%, and 11.9% for all indications outside of oncology"), https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

[198] *See* INT'L TRADE ADMIN., *supra* note 195, at 3. *See also* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 305 (2015).

[199] *See* INT'L TRADE ADMIN., *supra* note 195, at 3.

[200] *See* U.S. FOOD AND DRUG ADMIN., GENERIC COMPETITION AND DRUG PRICES, https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm (last visited Sept. 7, 2017).

[201] P.L. 111-148, 124 Stat. 804 (2010).

environment that aims to be hospitable to health innovation.[202] Of note, the Hatch-Waxman Act, which was signed into law in 1984[203] with the congressional intent of striking a balance between fostering innovation and advancing consumer interests, encourages the manufacture of generic drug products by establishing the abbreviated regulatory scheme for approving generic drugs and providing a framework for resolving consequent patent disputes.[204] Under federal law, in order for a new (i.e., "pioneer" or "brand name") drug to be marketed, a manufacturer must first obtain FDA approval of a new drug application (NDA).[205] As a prerequisite to submitting an NDA, the manufacturer must conduct, or arrange to conduct, clinical studies designed to show that the drug is safe and effective for its intended use in accordance with section 505(d) of the Food, Drug, and Cosmetic Act (FD&C Act).[206] Conversely, Hatch-Waxman's abbreviated pathway to approval for generic drugs created a new type of marketing application, the abbreviated new drug application (ANDA), which does not require clinical testing, but instead requires a third party or generic manufacturer to show that its drug formulation is a therapeutically equivalent copy of the brand name drug being marketed.[207]

Significantly, Hatch-Waxman also amends the FD&C Act to provide for periods of time in which a new drug is the exclusive drug on the market. These periods of market exclusivity provided for under food and drug law are sometimes referred to as a type of "regulatory exclusivity,"[208] which are in addition to and distinct from patent term exclusivity.[209] That is to say, market exclusivity under food and drug law may still be in effect even if the drug is not under patent protection. More specifically, the Hatch-Waxman Act provides a five-year period of market exclusivity for new molecular entities and three years of market exclusivity for a new use or new formulation of previously approved drug products.[210] To encourage the production of generic drugs,[211] the Hatch-Waxman Act also created a 180-day exclusivity period for the first approved generic version of a brand-name drug product.[212] Congress also provided additional market exclusivity under the Patent Act. In response to criticisms that the lengthy FDA approval process eroded the benefit of patent term market exclusivity, the Hatch-Waxman Act provided for "patent term restoration,"

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[202] *See id.*

[203] P.L. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271).

[204] *See* Kesselheim & Darrow, *supra* note 198, at 301 ("The Act was intended to make low-cost generics more widely available while simultaneously maintaining adequate incentives for innovation."); *see also* CRS Report R44643, *The Hatch-Waxman Act: A Primer*, at 6–7 (describing the framework for patent dispute resolution under Hatch-Waxman).

[205] *See* 21 U.S.C. 355.

[206] PETER BARTON HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, FOOD AND DRUG LAW, CASES AND MATERIALS 635 (3d ed. 2007); *see also* 21 U.S.C. 355(d).

[207] 21 U.S.C. § 355(j). As an alternative to filing an ANDA, Hatch-Waxman also allows for a generic manufacturer to file a "505(b)(2) application," which relies, at least in part, on the safety and efficacy data that the applicant did not itself develop, but that is available in the published literature. *See id.* § 355(b)(2); *see also* CRS Report R44643, *The Hatch-Waxman Act: A Primer*, at 5–6.

[208] *See* CRS Report R42890, *The Role of Patents and Regulatory Exclusivities in Pharmaceutical Innovation*, at 4.

[209] The term "regulatory exclusivity" is used to refer to any FDA-administered proprietary right and may be divided into two categories: (1) rights providing data exclusivity, also known as data protection, and (2) rights providing market exclusivity. *Id*.

[210] 21 U.S.C. § 355(j)(5)(F)(ii)–(iii).

[211] A generic drug is a "lower-cost copy of a brand-name chemical drug." CRS Report R44703, *Generic Drugs and GDUFA Reauthorization: In Brief*, by Judith A. Johnson.

[212] 21 U.S.C. § 355(j)(5)(B)(iv).

allotting additional time to the patent term of a pioneer drug in order to compensate the patent holder for the time lost during clinical trials and the FDA review process.[213]

More recently, in 2010, as part of the Patient Protection and Affordable Care Act,[214] Congress enacted the BPCIA for the stated purpose of "balancing innovation and consumer interests." While there are important differences between the two statutes, like Hatch-Waxman, the BPCIA sought to achieve this goal through changes to food and drug as well as patent law. With respect to food and drug law, the BPCIA establishes an abbreviated pathway for regulatory approval of "follow-on biologics" or "biosimilars"—lower-cost versions of biologics.[215] A "biological product" or "biologic" is a medical product made from natural resources (human, animal, microorganism) used in the prevention, treatment, or cure of disease.[216] The traditional route for FDA approval of a biological product for commercial marketing is through a biologics license. In order to obtain a license to market a biologic, a sponsor must complete a biologics licensing application (BLA), wherein the sponsor provides clinical data—the results of a costly multi-phase clinical trial process—demonstrating that the product is "safe, pure, and potent."[217] Under the BPCIA's abbreviated pathway, a biosimilar applicant filing an abbreviated biologics license application (aBLA) must, in order to receive approval, submit information sufficient to show that a product is "biosimilar" to or "interchangeable"[218] with a previously approved biologic (i.e., "reference product") and rely upon "publicly-available information regarding [FDA's] previous determination that the reference product is 'safe, pure, and potent.'"[219] In balancing innovation with competition, the BPCIA also provides for a 4-year and 12-year exclusivity period for a reference product wherein (1) an aBLA may not be *submitted* prior to the date that is 4 years after the date on which the reference product was first licensed and (2) *approval* of an aBLA may not be made effective until the date that is 12 years after the date on which the reference product was first licensed.[220] With respect to patent law, the BPCIA creates a process, discussed in greater detail below,[221] that endeavors to speed the litigation of patents, while protecting the innovator's patent rights.[222]

Impression Products v. Lexmark

On May 30, 2017, in a nearly unanimous decision, the Supreme Court reversed the Federal Circuit in a case respecting the doctrines of domestic and international patent exhaustion, holding in *Impression Products v. Lexmark International* that "a patentee's decision to sell a product exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to

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[213] 35 U.S.C. § 156(a).

[214] P.L. 111-148, § 7001–02, 124 Stat. 119, 804–06 (2010).

[215] *Id.* at 804.

[216] S*ee* 42 U.S.C. § 262(i)("The term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.").

[217] *See* 42 U.S.C. § 262(a); *see also* 21 C.F.R. § 600–80.

[218] "Interchangeable" biological products are technically distinct from "biosimilars," in that in addition to meeting the standard for biosimilarity, they must also produce the same clinical result as the reference product in any given patient. *See* 42 U.S.C. § 262(k)(2)(B).

[219] *See id*. § 262(k).

[220] *See id.* § 262(k)(7).

[221] *See* discussion *infra* in *Sandoz v. Amgen*.

[222] *See* 42 U.S.C. § 262(*l*).

impose or the location of the sale."[223] Although the case arose out of a dispute over printer cartridges, the question at the heart of the dispute—whether restrictions placed on the sale of a patented product are enforceable under patent law—has significant implications across a number of industries, particularly the pharmaceutical and medical device industries.[224]

To understand the *Impression Products* ruling, it is important to note several broad principles of patent law. In addition to providing a private right of action against anyone who, without authority from the patent holder, "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent," Section 1498 of Title 28 provides an express statutory means by which a patent holder can recover compensation for infringement of a patent by the federal government. Specifically, the statute provides that whenever a patent "is used or manufactured by or for the United States without license of the owner," the patent holder may bring an action in United States Court of Federal Claims to recover "his reasonable and entire compensation for such use and manufacture."[225] Patent holders also have certain ancillary rights, such as the right to license their patented products and the right to sell or license their patented products with restrictions, including via so-called "Single Use" provisions,[226] through contractual agreements.[227]

There is, however, a key limitation on the rights of patent holders called the doctrine of patent exhaustion. The common law "exhaustion doctrine" (also known as the "first sale doctrine") stands for the principle that once an authorized sale of a patented article occurs, the patent holder's exclusive rights to control the use and sale of that article under patent law are said to be "exhausted," freeing the purchaser to use or resell the article without restraint.[228] The basis for this principle, as articulated by the Supreme Court, is that "[t]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward ... by the sale of the article"; once that "purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold."[229] It is important to note, however, that the patent exhaustion doctrine applies only to the particular item sold and does not otherwise free a buyer to replicate or reproduce the patented item into a new product.[230] Prior to the Supreme Court's ruling in *Impression Products*, the Federal Circuit's prevailing precedent allowed patent holders to place post-sale use and resale restrictions on domestic sales[231] without implicating the doctrine of patent exhaustion and exempted sales abroad from the first sale doctrine entirely.[232] In other

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[223] Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1529 (2017).

[224] *See id*.

[225] 28 U.S.C. § 1498(a).

[226] "Single use" provisions refer to a common practice in label licensing, in which a patent owner may attempt to restrict a customer's use of a good by, for e.g., restricting use to a specific geographic location. *See* CRS Report R44032, *Patents and Regulatory Exclusivities: Issues in Pharmaceutical Innovation and Competition*.

[227] *See* STEPHEN P. LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION, Vol. 1, 438–39 (1975).

[228] *See* Quanta Computer, Inc. et al v. LG Electronics, Inc., 553 U.S. 617, 625 (2008) ("[T]he initial authorized sale of a patented item terminates all patent rights to that item.").

[229] Bowman v. Monsanto Co., 133 S. Ct. 1761, 1766 (2013) (citing United States v. Univis Lens Co., 316 U.S. 241, 251 (1942)).

[230] *See id*. at 1769 (noting that "Bowman planted Monsanto's patented soybeans solely to make and market replicas of them, thus depriving the company of the reward patent law provides for the sale of each article. Patent exhaustion provides no haven for this conduct.").

[231] *See* Mallincrodt, Inc. v. Medipart, Inc. 976 F.2d 700, 708 (Fed. Cir. 1992) (holding that post-sale use and resale restrictions may be enforced under patent law).

[232] *See* Jazz Photo Corp. v. Int'l Trade Comm'n, 264 F.3d 1094, 1105 (Fed. Cir. 2001) ("United States patent rights are

words, patent holders maintained the ability to (1) sue for infringement if restrictions placed on domestic sales were not observed and (2) recoup more than a single reward for the sale of a patented item if the first sale was made abroad. *Impression Products* explicitly overturned the Federal Circuit's precedent with respect to both issues, changing the legal landscape for patent holders.

The controversy at issue in *Impression Products* stems from certain practices of companies known as "remanufacturers" that violated restrictions Lexmark had placed on the sales of its patented printer cartridges.[233] Consumers had two options when purchasing toner cartridges from Lexmark—they could either buy the cartridge at full price with no restrictions, or they could buy the cartridge at a discount through Lexmark's "Return Program."[234] In order to receive the discounted price through the Return Program, however, customers had to sign a contract agreeing to use the cartridge only once and then return it to Lexmark.[235] Despite these restrictions, remanufacturers would acquire the Lexmark cartridges, including those initially sold through the Return Program, refill them with toner, and sell them at a discounted rate.[236] Remanufacturers also acquired Lexmark cartridges sold overseas, reimported them into the United States, and refilled and sold them along with the Return Program cartridges.[237]

Lexmark sued a number of these remanufacturers, including Impression Products, for patent infringement with respect to two groups of cartridges: (1) those cartridges sold as part of the Return Program within the United States on the theory that the prohibited reuse and resale of these products infringed Lexmark's patents;[238] and (2) all cartridges sold abroad that Impression Products imported into the United States on the theory that, because Lexmark never authorized the import of its cartridges, Impression Products infringed its patents by doing so.[239] Impression Products moved to dismiss on the grounds that Lexmark's sales, both in the United States and abroad, exhausted all patent rights and freed Impression Products to refurbish, resell, and import products acquired overseas.[240] The district court granted the motion with respect to the domestic Return Program sales,[241] but denied the motion as to the cartridges sold abroad based on Federal Circuit precedent.[242] On appeal, the Federal Circuit ruled in favor of Lexmark with respect to both groups of cartridges.[243]

The Supreme Court's decision to reverse the Federal Circuit with respect to both domestic and international patent exhaustion appears to rest on the underlying principle that, "when an item passes into commerce, it should not be shaded by a legal cloud on title as it moves through the

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not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent.").

[233] *See* Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1529 (2017).

[234] *Id.*

[235] *Id.*

[236] *See id.*

[237] *See id.*

[238] Lexmark owns a number of patents that cover various components of the printer cartridges. *See* Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1529–30 (2017).

[239] *See id*. at 1530.

[240] *See id*.

[241] Lexmark Int'l, Inc. v. Ink Techs. Printer Supplies, LLC, No. 1:10-CV-564, 2014 WL 1276133, at *7 (S.D. Ohio March 27, 2014).

[242] Lexmark Int'l, Inc. v. Ink Techs. Printer Supplies, LLC, 9 F. Supp. 3d 830, 838 (S.D. Ohio 2014).

[243] Lexmark Int'l, Inc. v. Impression Products, Inc., 816 F.3d 721, 773–74 (Fed. Cir. 2016).

marketplace."[244] Referring to its 2013 ruling in *Kirtsaeng v. John Wiley & Sons*, a case involving copyright law, the Court noted that "we have explained in the context of copyright law that exhaustion has an 'impeccable historic pedigree,' tracing its lineage back to the 'common law's refusal to permit restraints on the alienation of chattels.'"[245] In this manner, *Impression Products* can be viewed as an example of one in which the Court harmonizes an aspect of patent law with other areas of federal law, as discussed above.[246]

The Supreme Court reasoned that the Federal Circuit reached a different result because it "got off on the wrong foot."[247] The Court described the Federal Circuit's view that "exhaustion must be understood as an interpretation of the patent infringement statute."[248] The Federal Circuit, according to the Court, viewed exhaustion as not requiring a patentee to hand over the "full bundle of rights" every time it makes a sale, but rather allows a patentee to "withhold a stick from the bundle, perhaps by restricting the purchaser's resale rights."[249] The Court countered:

> The misstep in [the Federal Circuit's] logic is that that the exhaustion doctrine is not a presumption about the authority that comes along with a sale; it is instead a limit on "the scope of the patentee's rights." The right to use, sell, or import an item exists independently of the Patent Act. What a patent adds—and grants exclusively to the patentee—is a limited right to prevent others from engaging in those practices. Exhaustion extinguishes that exclusionary power. As a result, the sale transfers the right to use, sell, or import because those are rights that come along with ownership, and the buyer is free and clear of an infringement lawsuit because there is no exclusionary right left to enforce.[250]

With respect to international patent exhaustion, commentators had, prior to this ruling, questioned *Kirtsaeng*'s application to international patent exhaustion, noting distinctions between copyright and patent law. Namely, unlike the first-sale doctrine in copyright law, commentators noted that patent exhaustion has not been codified, and patent rights have a territorial requirement restricting their reach to the United States.[251] Likewise, in refusing to extend patent exhaustion extraterritorially, the Federal Circuit also emphasized distinctions between copyright and patent law, in particular the difference in breadth of scope. Specifically, while patent law affords the right to exclude others from use, copyright law does not. The Supreme Court, however, took another position.[252] Noting that "patent exhaustion, too, has its roots in the antipathy toward restraints on alienation," the Court stated that "applying patent exhaustion to foreign sales is just as straightforward" as applying the first sale doctrine to foreign sales of copyrighted works.[253] To this end, the Court emphasized that "nothing in the text or history of the Patent Act shows that

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[244] Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1534 (2017).

[245] *Id*. at 1532 (citing Kirtsaeng v. John Wiley & Sons, Inc., 568 U.S. 519, 538 (2013)).

[246] *See* discussion *supra* in *Proceedings Before the Federal Courts*.

[247] *Lexmark*, 137 S. Ct.at 1533.

[248] *Id*.

[249] *Id*. at 1533–34 (citing *Lexmark*, 816 F.3d at 734, 741–42).

[250] *Id*. at 1534.

[251] *See* Wilson Elser, *Supreme Court Declines to Decide Whether the "First Sale Doctrine" Should Apply to Patent Law*, LEXOLOGY (Apr. 1, 2013), https://www.lexology.com/library/detail.aspx?g=89239bb1-d585-4a38-8f6b-6cd93574b6fe; Foley & Lardner LLP, *Copyright and Patent Implications of Supreme Court's First Sale Doctrine Ruling*, LEGAL NEWS ALERT: IP LITIGATION (Mar. 22, 2013), https://www.foley.com/copyright-and-patent-implications-of-supreme-courts-first-sale-doctrine-ruling-03-22-2013/; Timothy Toohey and Keith Gregory, *Parallel Imports and the First Sale Doctrine*, SNELL & WILMER, https://www.swlaw.com/assets/pdf/news/2011/11/14/ParallelImportsandtheFirstSaleDoctrine_Toohey_Gregory.pdf.

[252] *See* Lexmark Int'l, Inc. v. Impression Prods., Inc., 816 F.3d 721, 756–61 (Fed. Cir. 2016).

[253] Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1536 (2017).

Congress intended to confine that borderless common law principle to domestic sales. In fact, Congress has not altered patent exhaustion at all; it remains an unwritten limit on the scope of the patentee's monopoly."[254]

While the Supreme Court's decision in *Impression Products* suggests that patent law may not be used as a mechanism for enforcing restrictions on the sale of patented items, the Court clarified that such restrictions may remain enforceable under contract law:

> If there were any lingering doubt that patent exhaustion applies even when a sale is subject to an express, otherwise lawful restriction, our recent decision in *Quanta Computer, Inc. v. LG Electronics, Inc.*, settled the matter ... without so much as mentioning the lawfulness of the contract, we held that the patentee could not bring an infringement suit because the "authorized sale ... took its products outside the scope of the patent monopoly." Turning to the case at hand ... whatever rights Lexmark retained are a matter of the contracts with its purchasers, not the patent law. [255]

Moreover, in a passage that may be of particular importance for patentees that often license others to make and sell their patented products under certain conditions, the Court explained how a license of a patented product may implicate the exhaustion doctrine. The Court noted:

> A patentee can impose restrictions on licensees because a license does not implicate the same concerns about restraints on alienation of sale ... a license is not about passing title to product, it is about changing the contours of the patentee's monopoly: The patentee agrees not to exclude a licensee from making or selling the patented invention, expanding the club of authorized producers and sellers. Because the patentee is exchanging rights, not goods, it is free to relinquish only a portion of its bundle of patent protections.[256]

At the same time, the Court emphasized that the ability to place restrictions on licenses did not provide a mechanism for circumventing patent exhaustion. The Court explained that "so long as a licensee complies with the license when selling an item, the patentee has, in effect, authorized the sale," thereby exhausting the patent.[257] The Court also reiterated that, in the event the purchaser did not comply with the restrictions, "the only recourse for the licensee is through contract law, just as if the patentee itself sold the item with a restriction."[258]

Contract law, however, offers significantly less protection for patent holders, as it reaches only as far as the parties in privity with the original contract.[259] That is to say, once the patented item moves beyond the initial transaction, any restrictions made under the original contract will likely not be enforceable against new purchasers downstream.[260] Contract law also provides less protection compared to patent law in terms of damages. As noted, the Patent Act provides for damages "adequate to compensate for the infringement," and courts are granted the discretion to

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[254] *Id*.

[255] *Id*. at 1533.

[256] *Id*. at 1534.

[257] *Id*. at 1534–35.

[258] *Id*. at 1523.

[259] *See* RESTATEMENT (SECOND) OF CONTRACTS § 302 (Am. Law Inst. 1981); *see also* J. H. Reichman and Pamela Samuelson, *Intellectual Property Rights in Data*?, 50 VAND. L. REV. 51, 137 (1997) ("Even contract law has significant limitations when mass-marketed information products are sold to persons not in privity with the makers.").

[260] *See* Yellow Pages Photos, Inc. v. Ziplocal, LP, 795 F.3d 1255, 1268 (11th Cir. 2015) ("Like the 'first sale' doctrine, the 'patent exhaustion' doctrine enabled downstream users who were not parties to initial contracts to make arguments about the validity of those contracts.").

grant enhanced (i.e., treble) damages.[261] By contrast, under contract law damages are more limited—the injured party may recover damages to cover losses incurred by the breach, but treble damages are unavailable.[262] With patent infringement no longer an available mechanism for enforcing post-sale restrictions, it is likely that many existing contracts will need to be renegotiated and that patent holders will be increasingly scrupulous in entering into future contracts, particularly with foreign parties.[263]

Prior to the Supreme Court's decision in *Impression Products*, Federal Circuit precedent regarding patent exhaustion provided significant protections for patent holders by allowing them to enforce post-sale restrictions through patent infringement actions and rejecting international patent exhaustion.[264] This legal climate, along with an increasingly global market for medical products, provided fertile ground for what is now, as commentators have noted, an entrenched business practice—the heavy use of restrictions on the domestic and international sales of patented products—within the pharmaceutical and medical device industries.[265] Thus, as reflected in the amici briefs[266] filed prior to the Supreme Court's *Impression Products* ruling, the Court's conclusion that "patent exhaustion is uniform and automatic" may have significant implications for pharmaceutical and medical device companies.[267]

Pharmaceutical companies have argued that changes to the legal landscape that limit patent rights would stifle innovation, ultimately hurting the public health.[268] More particularly, the industry has long argued that patent and other regulatory exclusivities, like those provided for under the FD&C Act, are a means of recouping investments in research and development.[269] The Supreme Court's ruling with respect to international patent exhaustion, in particular, has potentially significant implications for this industry. It is no secret that drugs are sold at different prices in different countries for a number of reasons—including that drug prices in some markets are set not by the free market, but by the foreign government; patent rights are weaker under some foreign regimes, driving down prices; and, given disparities in global wealth, some foreign markets cannot support drugs at a revenue-generating cost.[270] As such, there is concern among

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[261] *See* discussion *infra* in *Rights of Patent Holders*.

[262] *See* RESTATEMENT (SECOND) OF CONTRACTS § 347 (Am. Law Inst. 1981).

[263] Shamita Etienne-Cummings et al., *Supreme Court's Lexmark Decision Exhausts Patents*, WHITE AND CASE NEWSFLASH, (June 12, 2017), https://www.whitecase.com/publications/article/supreme-courts-lexmark-decision-exhausts-patents ("Further consideration should be made in drafting [contracts] to include provisions to better support a potential breach of contract claim since a patent infringement claim is no longer available.").

[264] *See, e.g.*, Mallinkrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 709 (1992) (concluding that "the district court erred in holding that the restriction on reuse was, as a matter of law, unenforceable under patent law."); Jazz Photo Corp. v. Int'l Trade Comm'n., 264 F.3d 1094, 1111 (2001) (holding that "LFFPs whose prior sale was not in the United States ... remain subject to the Commission's orders" on the basis that patent exhaustion does not apply to a first sale made abroad.").

[265] *See* Barbara A. Fiacco, et al., *Supreme Court Limits Patent Owners' Ability to Control Post-Sale Use of Patented Products*, INTELLECTUAL PROPERTY ALERT, FOLEY HOAG LLP (June 9, 2017), http://www.foleyhoag.com/publications/alerts-and-updates/2017/june/supreme-court-limits-patent-owners-ability-to-control-post-sale-use-of-patented-products.

[266] *See generally* Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Respondent, Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[267] Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1535 (2017).

[268] *See* Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Respondent at 11, Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[269] *See* CRS Report R44032, *Patents and Regulatory Exclusivities: Issues in Pharmaceutical Innovation and Competition*, by John R. Thomas.

[270] *See* CRS Report R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy*, by Suzanne M. Kirchhoff, Judith A. Johnson, and Susan Thaul; *see also* Brief for Pharmaceutical Research and Manufacturers of

industry representatives that *Impression Products*' extension of patent exhaustion to foreign sales could expand grey market sales—that is, products bought and sold outside the manufacturer's authorized trading channels—of medicines originally sold in foreign markets at lower prices.[271] According to this view, an expansion of grey market sales may, in turn, upset the balance between innovation and patient access that Congress intended to strike through statutory and regulatory mechanisms.[272] As examples of these mechanisms, U.S. patent law provides for U.S. market exclusivity and protection from infringement,[273] while additional regulatory exclusivities for various categories of innovative medical products are provided for under laws implemented by FDA.[274] In addition, FDA is authorized to enforce restrictions on the importation of medical products.[275] In the views of at least one amicus brief, the expansion of grey market sales could result in limiting patient access to medications by limiting the incentive for innovation.[276]

That said, given current regulatory restrictions on the importation of medical products, the law provides pharmaceutical companies with more protection than most other manufacturers with respect to the reimportation of goods sold abroad. Specifically, FD&C Act section 801(d)(1) prohibits anyone other than the manufacturer from reimporting drugs manufactured in the United States and sold abroad.[277] Relying on this provision, one consumer advocacy group has argued that the statute "effectively prevents large-scale parallel importation of drugs originating in the United States and thus renders the impacts predicted by [industry] unlikely."[278]

Economic consequences may not be the only issues raised by the Supreme Court's decision scaling back a patentee's ability to enforce post-sale restrictions through patent infringement actions. In addition to economic concerns, the medical device industry argues that compromising the enforcement of restrictions on single-use devices (SUDs), which range in sophistication from compression sleeves to cardiac catheters, may pose public health risks.[279] SUDs, which emerged in response to heightened awareness about the transmission of infectious diseases, are manufactured with the expectation that they will be discarded after one single use in one single patient.[280] Because SUDs are not designed or constructed to be cleaned for subsequent use, some are made of materials that are unable to withstand necessary resterilization procedures.[281]

America as Amicus Curiae in Support of Respondent at 12–19, Impression Products v. Lexmark Int'l, Inc., No. 15-1189, slip op. (S. Ct. May 30, 2017).

[271] *See* Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Respondent at 15, Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[272] *Id*.

[273] *See* 35 U.S.C. §§ 154, 271.

[274] *See* CRS Report R44032, *Patents and Regulatory Exclusivities: Issues in Pharmaceutical Innovation and Competition*.

[275] *See* 21 U.S.C. § 381.

[276] *See* Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Respondent at 18, Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[277] 21 U.S.C. § 381(d)(1); *see also id.* § 332(b) (stating that any person who knowingly violates section 801(d)(1) of the FD&C Act shall be imprisoned for not more than 10 years or fined not more than $250,000, or both).

[278] Brief of Amicus Curiae Public Citizen, Inc. in Support of Petitioner at 5, Impression Products, Inc. v. Lexmark Int'l, 137 S. Ct. 1523 (2017) (No. 15-1189).

[279] Brief of Amicus Curiae, Medical Device Manufacturers Association in Support of Respondent at 4–9, Impression Products v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[280] *See id*. at 4–5.

[281] *See id*. at 5.

As background, medical devices that are more complex and higher risk[282] are typically required to obtain FDA approval prior to marketing through an application for premarket approval (PMA), which similar to an NDA, requires clinical testing to show a "reasonable assurance of safety and effectiveness" to market a device.[283] Some less complex and lower-risk devices are eligible to instead obtain clearance for marketing through a 510(k) submission if the product is shown to be "substantially equivalent" to a predicate product (i.e., a device already on the market).[284] FDA regulates the common cost-saving mechanism of reprocessing—the collection of discarded medical devices for cleaning, repair, and resterilization in preparation for resale—by requiring that manufacturers of reusable devices test and supply instructions for safe reprocessing[285] and that reprocessors of SUDs demonstrate "substantial equivalence" in terms of safety and efficacy to the original manufactured product.[286] Given that reprocessing is regulated by FDA, one may question whether post-sale restrictions are necessary to ensure safety with regard to SUDs. However, FDA itself has stated that "[r]educing the risk of exposure to improperly reprocessed medical devices is a shared responsibility among various stakeholders ... [including] manufacturers.... "[287] Because SUDs are intended for use only once and may not—at least in some instances—be safely refurbished, manufacturers of SUDs, unlike manufacturers of reusable medical devices, are not, however, required to provide reprocessing instructions.[288] Thus, the Medical Device Association argued in its amicus brief in *Impression Products* that "if all post-sale restrictions are ineffective, medical device manufacturers will be unable to ensure compliance with the guidelines for safely reprocessing reusable devices."[289] On the other hand, it seems unlikely that all single-use restrictions would be rendered entirely ineffective by the Supreme Court's decision on patent exhaustion, as FDA still requires reprocessors to demonstrate the safety and efficacy of a refurbished SUD.[290] Furthermore, other laws, such as state tort law or consumer protection laws, could (subject to federal preemption limits) serve as a disincentive for

[282] *See* 21 U.S.C. § 360c (classifying medical devices into three risk-based categories; class III devices are typically required to obtain premarket approval through a PMA).

[283] *See id.* § 360e(c).

[284] *See id.* § 360(c)(i), (k); *see also* 21 C.F.R. § 807.87 (establishing the requirements for premarket notifications to be submitted by device manufacturers in support of substantial equivalence).

[285] *See* U.S. FOOD & DRUG ADMIN., REPROCESSING MEDICAL DEVICES IN HEALTH CARE SETTINGS: VALIDATION METHODS AND LABELING GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 4 (2015), https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf [hereinafter *FDA Guidance-Medical Device Reprocessing*]; *see also* Jaimy Lee, *Repositioning Reprocessing: Hospitals See Big Potential for Savings, but Safety Remains an Issue for Some*, MODERN HEALTHCARE (July 6, 2013), http://www.modernhealthcare.com/article/20130706/MAGAZINE/307069957.

[286] *See* U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002, VALIDATION DATA IN PREMARKET NOTIFICATION SUBMISSIONS (510(K)S) FOR REPROCESSED SINGLE-USE MEDICAL DEVICES 4 (2006), https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071441.pdf. [hereinafter *FDA Guidance-510(k) Requirements for Reprocessed Medical Devices*].

[287] U.S. FOOD & DRUG ADMIN., MEDICAL DEVICES: WORKING TOGETHER TO IMPROVE REUSABLE MEDICAL DEVICE REPROCESSING (April, 8, 2016) https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454626.htm.

[288] *See FDA Guidance-Medical Device Reprocessing*, *supra* note 285, at 2–3 (noting a limited exception: single use medical devices initially supplied as nonsterile to the user, and requiring the user to process the device prior to its use are required to supply reprocessing instructions).

[289] Brief of Amicus Curiae, Medical Device Manufacturers Association in Support of Respondent at 13, Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[290] *See FDA Guidance-510(k) Requirements for Reprocessed Medical Devices*, *supra* note 286, at 4.

a reprocessor's failure to heed a manufacturer's single-use restriction where reuse risks public safety.[291]

Finally, while *Impression Products* held that post-sale restrictions are not enforceable under patent law, it also clarified that contract law remains an appropriate vehicle for remedying such violations.[292] As previously discussed, contract remedies extend only to parties in privity with the agreement, and with respect to concerns raised by the pharmaceutical industry, contract law cannot reach downstream sales where grey market transactions are likely to occur.[293] Likewise, because many reprocessors are independent of the hospitals and health care facilities to which the devices were originally sold, there could be situations in which patent owners are without the requisite privity to base a breach of contract claim for violating post-sale restrictions on SUDs.[294] While it remains to be seen how significant the Supreme Court's reversal of the Federal Circuit's position on patent exhaustion will be on the pharmaceutical and medical device industries, the myriad questions raised by the *Impression Products* decision implicate the recurrent theme of balancing innovation and competition and thus may be of interest to Congress and the subject of future legislative debate.

Sandoz v. Amgen

Another Supreme Court opinion issued this term with significant implications for consumers and pharmaceutical companies is *Sandoz v. Amgen*,[295] issued on June 12, 2017. This case will potentially affect the speed at which competition emerges for many pharmaceutical products. Specifically, the Supreme Court considered opposing views on how to interpret key provisions in the BPCIA.[296]

As noted above, in 2010, as part of the Patient Protection and Affordable Care Act,[297] Congress enacted the BPCIA for the stated purpose of "balancing innovation and consumer interests" with the establishment of an abbreviated pathway for regulatory approval of biological products that are "highly similar" to or "interchangeable" with a previously approved FDA-licensed reference product ("reference product").[298] As part of this new abbreviated regulatory pathway for so-called "biosimilars" and particularly relevant to *Sandoz*, the BPCIA sets forth a complex patent-dispute resolution regime wherein the reference product owner can protect against potential infringements of any patents of products that are the subject of an aBLA.[299] Thus, rather than waiting until commercial marketing to resolve disputes, the BPCIA facilitates litigation during the period preceding FDA approval.[300] In doing so, the BPCIA "enables the parties to bring infringement actions at certain points in the application process, even if the applicant has not yet

[291] *See generally* CRS Report R43218, *Preemption of Drug and Medical Device Claims: A Legal Overview*, by Andrew Nolan and Jennifer A. Staman.

[292] Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523, 1535 (2017).

[293] *See* Brief for Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Respondent at 18, Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[294] *See* Brief of Amicus Curiae, Medical Device Manufacturers Association in Support of Respondent at 9–10, Impression Products, Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189).

[295] Sandoz, Inc. v. Amgen, Inc., 137 S. Ct. 1664, 1669–70 (2017).

[296] *See id*. at 1664–78.

[297] P.L. 111-148, § 7001–02, 124 Stat. 119, 804–06 (2010).

[298] *Id.* at 804.

[299] *See* Sandoz, Inc. v. Amgen, Inc., 137 S. Ct. 1664, 1669–70 (2017).

[300] *Id*. at 1670.

committed an act that would traditionally constitute patent infringement ... [the BPCIA] provides that the mere submission of a biosimilar application constitutes an act of infringement."[301] The Supreme Court has referred to this type of "preapproval infringement" as "artificial infringement."[302]

More specifically, by amending section 262 of the Public Health Service Act,[303] the BPCIA establishes an elaborate process for patent dispute resolution, sometimes referred to as the "patent dance."[304] The "dance" generally involves an applicant and reference product sponsor (i.e., "the sponsor") participating in a series of informational exchanges regarding potential disputes over patent validity and infringement prior to marketing of the biosimilar.[305]

The Disclosure Requirement: Of particular relevance to *Sandoz*, the initial requirement under the BPCIA's disclosure and negotiation procedures is that the applicant "shall" grant the reference product sponsor confidential access to its aBLA application and the manufacturing information regarding the biosimilar product no later than 20 days after FDA accepts the application for review.[306] From this disclosure, the exchange continues: pursuant to section 262(*l*)(3), within 60 days of disclosure, the sponsor "shall provide" to the applicant "a list of patents" for which it believes it could assert an infringement claim if a person without a license made, used, offered to sell, sold, or imported "the biological product that is the subject of the [biosimilar] application."[307] At this time the sponsor also identifies any patents on the list that it would be willing to license.[308] In turn, within 60 days of receiving the sponsor's list, the applicant may provide the sponsor with a list of patents that it believes are relevant, but were omitted from the sponsor's list.[309] Next, the applicant "shall provide" to the sponsor the reasons why it could not be held liable for infringing those patents, for example because the patents are invalid, unenforceable, or not infringed.[310] The applicant must also, if applicable, respond to the sponsor's offer to license particular patents.[311] The sponsor then "shall provide" within 60 days responses to the applicant's arguments concerning infringement, enforcement, and validity, as to each relevant patent.[312]

The Notice Requirement: In another relevant provision of the BPCIA, the law provides that the applicant "shall" give notice of commercial marketing to the reference product sponsor at least 180 days prior to commercial marketing.[313] This notice provides the reference product sponsor a period of time to seek a preliminary injunction to enjoin infringing acts. Furthermore, either party

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[301] *Id*.

[302] *Id*.

[303] *See* 42 U.S.C. § 262.

[304] *See* Dov Hirsch, *The Riddle of the Mysterious Patent Dance Wrapped in an Enigma: Is the Patent Dance of the BPCIA Optional or Mandatory*?, 27 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 645, 649 (2017) (noting that the term "patent dance" is used to refer to the "structured patent dispute resolution process of the BPCIA").

[305] *See* 42 U.S.C. § 262(*l*).

[306] *See id*. § 262(*l*)(2)(A).

[307] *See id*. § 262(*l*)(3)(A)(i). *See also* Sandoz, Inc. v. Amgen, Inc., 137 S. Ct. 1664, 1669–70 (2017).

[308] 42 U.S.C. § 262(*l*)(3)(A)(ii).

[309] *Id*. § 262(*l*)(3)(B)(i)–(ii).

[310] *Id*.

[311] *Id*. § 262(*l*)(3)(B)(iii).

[312] *Id*. § 262(*l*)(3)(C).

[313] *Id*. § 262(*l*)(8)(A).

may sue for declaratory relief, but the parties are barred from doing so prior to the applicant's notice of commercial marketing.[314]

Two-Phased Litigation: The Supreme Court's decision in *Sandoz v. Amgen* describes these mechanics as "channel[ing] the parties into two phases of patent litigation": (1) upon disclosure of the application and manufacturing information, the parties collaborate to identify patents for immediate litigation; and (2) upon notice of commercial marketing, the parties may litigate patents that were included on the section 262(*l*)(3) lists, but not litigated in the first phase.[315] Thus, if the parties comply with the "patent dance," they will have the opportunity to litigate any relevant patents prior to commercial marketing.[316]

Remedial Provisions: In order to encourage the parties to comply, the BPCIA also includes consequences for failing to do so.[317] Two of these remedial provisions were of particular relevance in *Sandoz*. First, if the applicant fails to comply with the disclosure requirement, which effectively commences the two-phase litigation process, then the sponsor, but not the applicant, may immediately bring a declaratory action for infringement.[318] Similarly, if the applicant fulfills the disclosure requirement, but fails to comply with the subsequent steps in the information exchange process, the applicant, but not the sponsor, may bring a declaratory judgment action with respect to any patent included on the sponsor's section 262(*l*)(3) list.[319] In both instances, the BPCIA facilitates these actions by making it an artificial act of infringement to submit a biosimilar application with respect to any patent that could have been included on the section 262(*l*)(3) list.[320]

The impetus behind the *Sandoz* litigation was Sandoz's first FDA approval under the BPCIA's new regulatory pathway for its product "Zarxio," a biosimilar for the FDA-approved anti-infective biologic filgrastim, and the first biosimilar approved under the BPCIA.[321] Amgen, the company that has produced and marketed filgrastim under the brand name "Neupogen" since 1991, filed suit in the Northern District of California for patent infringement under 42 U.S.C. § 262(*l*)(9)(c).[322] Amgen also sought an injunction in an effort to forestall market entry of Zarxio with claims grounded in two alleged violations of the BPCIA—Amgen claimed that Sandoz's failure to comply with the disclosure and negotiation procedures established by the BPCIA and its interpretation of a 180-day notice requirement both comprised actionable unlawful business practices under California law.[323]

With regard to participation in the BPCIA's disclosure and negotiation procedures, both the district court and the Federal Circuit held that those procedures—despite the use of the word "shall" in the statute—were not a *mandate* on the applicant.[324] Rather, the lower courts viewed the

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[314] *Id*. § 262(*l*)(9)(A).

[315] *See* Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1672 (2017).

[316] *Id*.

[317] *Id*.

[318] 42 U.S.C. § 262(*l*)(9)(C).

[319] *Id*. § 262(*l*)(9)(B).

[320] *See id*. § 271(e)(2)(C); *see also* Sandoz, Inc. v. Amgen, Inc., 137 S. Ct. 1664, 1672 (2017).

[321] Sandoz, 137 S. Ct. at 1673.

[322] *Id*.

[323] *Id*.

[324] *See* Amgen, Inc. v. Sandoz Inc., No. 14-cv-04741-RS, 2015 WL 1264756, at *6 (N.D. Cal. Mar. 19, 2015) (reasoning "that an action 'shall' be taken does not imply it is mandatory in all contexts. It is fair to read subsection (*l*) to demand that, if both parties wish to take advantage of its disclosure procedures, then they 'shall' follow the

disclosure and negotiation procedures as an *option* that confers certain benefits, largely in the form of reduced patent infringement litigation risks, in exchange for expediency in getting the product to market.[325] Furthermore, the Federal Circuit held that an injunction was unavailable as a remedy under federal law because "42 U.S.C. section 262(*l*)(9)(C) and 35 U.S.C. 271(e) expressly provide the only remedies" for violating the disclosure requirement, with neither authorizing a court to compel compliance.[326]

While the district court held that the 180-day notice provision should be interpreted to allow the applicant to give notice to the reference product sponsor *prior* to FDA approval of the aBLA,[327] the Federal Circuit vacated that holding in a split decision, maintaining that in order for notice to be effective, it must be given *after* the biosimilar is licensed by FDA.[328] The Federal Circuit's interpretation of the notice requirement would have functionally provided the reference product sponsor with an additional six months of market exclusivity because the applicant could only begin to sell the biosimilar product 180 days after the FDA ended the sponsor's exclusive right to sell the biologic.[329] Notably, the Federal Circuit seemed to suggest that the 180-day notice requirement is mandatory only if the applicant chooses to forgo the patent dance, stating that "where, as here, a[n] ... applicant completely fails to provide its aBLA and the required manufacturing information to the [reference product sponsor] by the statutory deadline, the [notice] requirement ... is mandatory."[330] In other words, the Federal Circuit's interpretation of the "shall" language with regard to the 180-day notice provision seemed to transform a requirement into something more optional.

The Supreme Court addressed two questions arising from the dispute: (1) whether the requirement that an applicant provide its application and manufacturing information to the manufacturer of the biologic is enforceable by injunction and (2) whether the applicant must give notice to the manufacturer after, rather than before, obtaining a license from the FDA for its biosimilar.[331]

With respect to the first question, the Supreme Court explained that Sandoz's failure to disclose its application and manufacturing information did not amount to an act of "artificial infringement" remediable by injunctive relief under the BPCIA.[332] The Court explained that the Federal Circuit erred in its apparent conclusion that noncompliance with section 262(*l*)(2)(A)

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prescribed procedures; in other words, these procedures are 'required' where the parties elect to take advantage of their benefits, and may be taken away when parties 'fail.'"); Amgen, Inc. v. Sandoz, Inc., 794 F.3d 1347, 1355–56 (Fed. Cir. 2015) (reasoning that "the 'shall' provision in paragraph (*l*)(2)(A) cannot be read in isolation ... latter provisions indicate that 'shall' in paragraph (*l*)(2)(A) does not mean 'must.' And the BPCIA has no other provision that grants a procedural right to compel compliance with the disclosure requirement of paragraph (*l*)(2)(A)").

[325] *Id*.

[326] Amgen, Inc. v. Sandoz, Inc., 794 F.3d 1347, 1356–57 (Fed. Cir. 2015).

[327] Amgen, Inc. v. Sandoz, Inc., No. 14-cv-04741-RS, 2015 WL 1264756, at *8 (N.D. Cal. Mar. 19, 2015) (holding that "the more persuasive interpretation accounts for the fact that FDA approval must precede market entry ... upon [a biosimilar's] 'first commercial marketing' a biosimilar must, in all instances, be a 'licensed' product. 'Before' modifies 'first commercial marketing;' 'licensed' refers only to 'biological product'—not the appropriate time for notice.").

[328] *Amgen*, 794 F.3d at 1356 (holding that "a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product.").

[329] *Id*. at 1358.

[330] *Id*. at 1359.

[331] Sandoz, Inc. v. Amgen Inc., 137 S. Ct. 1664, 1669 (2017).

[332] *Id*. at 1674.

(i.e., the disclosure requirement) is an "element of the artificial act of infringement."[333] Specifically, the Court noted that the Federal Circuit based its interpretation on the language in section 271(e)(2)(C)(ii), which states that "[i]t shall be an act of infringement to submit[,] *if the applicant for the application fails to provide the application and information* [to the reference product sponsor]." Rather, the Court held that such language "merely assists in identifying which patents will be the subject of an artificial infringement suit. It does not define the act of artificial infringement itself."[334] The Court reached this conclusion based on the structure of 271(e), which defines artificial infringement in two separate clauses—once within the context of the list exchange process and once when an applicant fails to disclose its manufacturing information.[335] The Court concluded that in both instances it is the act of submitting the application, rather than a failure to disclose information, that constituted the act of artificial infringement for which a remedy is provided under section 271(e)(4).[336] Instead, the Court held that a separate provision under section 262 of the BPCIA provides a remedy for an applicant's failure to turn over its application and manufacturing information—"§262(*l*)(9)(C) authorizes the sponsor, but not the applicant, to bring an immediate declaratory judgement action" for artificial infringement as defined in section 271(e)(2)(C)(ii).[337] The Court also noted, "§262(*l*)(9)(C) excludes all other federal remedies, including injunctive relief. Where, as here, 'a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies.'"[338] While concluding that an injunction was unavailable under federal law as a means of enforcing the disclosure requirement, the Court remanded the decision to the Federal Circuit to determine whether an injunction is available under California law.[339]

With respect to the second question presented, the Court reasoned that the plain language of the statute, which requires a biosimilar applicant to provide notice to the reference product sponsor "not later than 180 days before" the date of first commercial marketing of the biosimilar product, does not require the notice to occur after FDA licenses the product.[340] The Court explained:

> The applicant must give "notice" at least 180 days "before the date of commercial marketing." "[C]ommercial marketing," in turn, must be "of the biological product licensed under subsection (k)." Because this latter phrase modifies "commercial marketing" rather than "notice," "commercial marketing" is the point in time by which the biosimilar must be "licensed." The statute's use of the word "licensed" merely reflects the fact that, on the "date of first commercial marketing," the product must be "licensed." Accordingly, the applicant may provide notice either before or after receiving FDA approval.[341]

In support of this interpretation, the Court cited statutory context. Dismissing the lower court's position, the Court explained that, while section 262(*l*)(8)(A) contains a single timing requirement—an applicant must provide notice 180 days prior to marketing—"[t]he Federal Circuit ... interpreted the provision to impose two timing requirements: The applicant must

[333] *Id*.

[334] *Id*.

[335] *Id*.

[336] *Id*. at 1674–75.

[337] *Id*. at 1675.

[338] *Id*. at 1675 (citing Karahalios v. Federal Employees, 489 U.S. 527, 533 (1989)).

[339] *Id*. at 1675–76 (explaining that "[w]hether Sandoz's conduct was "unlawful" under [California's] unfair competition law is a state-law question, and the court below erred in attempting to answer that question by referring to the BPCIA alone.").

[340] *Id*. at 1677.

[341] *Id*. (quoting 42 U.S.C. §§ 262(a)(1)(A), (*l*)(8)(A)).

provide notice after the FDA licenses the biosimilar and at least 180 days before the applicant markets the biosimilar."[342] The Supreme Court went on to explain that "'[h]ad Congress intended to' impose two timing requirements in §262(*l*)(8)(A)," it "presumably" would have structured those requirements parallel to the two timing requirements in the subparagraph that immediately follows.[343]

The Supreme Court's decision in *Sandoz* has the potential to hasten the pace at which a biosimilar can reach the market by effectively making the "patent dance" optional. In other words, under *Sandoz* an applicant can choose not to engage in the disclosure and negotiation process with the reference product sponsor prior to marketing in exchange for assuming increased litigation risks. By refusing to adopt the Federal Circuit's interpretation of the BCPIA, the Supreme Court rejected an interpretation of the Act that would have effectively added 180 days of exclusivity for the sponsor.[344] Legal and industry experts have been vocal in their reactions to the Court's decision—some have questioned the meaningfulness of notice provided prior to approval, while others have suggested that the rejection of the availability of injunctive relief for enforcing a violation of the BPCIA effectively guts the protections Congress presumably sought to provide.[345] There is also concern that by loosening the requirements of the BPCIA, the Court's decision may create more uncertainty for innovator companies, biosimilar companies, and ultimately the general public alike.[346] For those who may question the outcome, Justice Breyer's concurrence offers an alternative—in line with his comments during oral argument, he stated that "if [FDA], after greater experience administering this statute, determines that a different interpretation would better serve the statute's objectives, it may well have authority to depart from, or to modify, today's interpretation."[347] Whether or not FDA acts to address the implications of the Court's decision, Congress could, should it feel the Supreme Court's interpretation is not reflective of the policy decisions intended, amend the BPCIA to clarify its provisions.

Emerging Issues in Patent Law

In addition to the effects of the patent decisions issued by the Supreme Court during its October 2016 Term, there are a number of patent-related issues on the horizon. Such issues stem from future Supreme Court cases to be heard during its next term; legislative proposals in Congress; and executive initiatives in the intellectual property area.

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[342] *Id*.

[343] *Id*. (citing Russello v. United States, 464 U.S. 16, 23) (1983).

[344] Amgen, Inc. v. Sandoz, Inc., 794 F.3d 1347, 1358 (Fed. Cir. 2015) (explaining that as a consequence of the Court's ruling, "Amgen will have an additional 180 days of market exclusion after Sandoz's effective notice date; that is because Sandoz only filed its aBLA 23 years after Amgen obtained FDA approval of its Neupogen product… That extra 180 days will not likely be the usual case, as aBLAs will often be filed during the 12-year exclusivity period for products.").

[345] *See* Erika Lietzan, *Sandoz v. Amgen: What the Court Settled, What it Didn't, And What Might Come Next*, HEALTH AFFAIRS BLOG (June 19, 2017), http://healthaffairs.org/blog/2017/06/19/sandoz-v-amgen-what-the-court-settled-what-it-didnt-and-what-might-come-next/; Gene Quinn, *Industry Reaction to SCOTUS decision in Sandoz v. Amgen*, IPWATCHDOG (June 14, 2017), http://www.ipwatchdog.com/2017/06/14/industry-reaction-scotus-sandoz-v-amgen/id=84473/.

[346] *See* Gene Quinn, *Industry Reaction to SCOTUS decision in Sandoz v. Amgen*, IPWATCHDOG (June 14, 2017), http://www.ipwatchdog.com/2017/06/14/industry-reaction-scotus-sandoz-v-amgen/id=84473/.

[347] Sandoz, Inc. v. Amgen Inc., 137 S. Ct. 1664, 1678 (2017).

Viability of Inter Partes Review Proceedings

As noted, the PTO's inter partes review proceedings are one of the major patent reforms made by the AIA,[348] but their continued availability is contingent on the judgment of the Supreme Court. Specifically, on June 12, 2017, the Supreme Court granted certiorari in *Oil States Energy Services v. Greene's Energy Group* on the sole question as to "[w]hether *inter partes* review—an adversarial process used by the [PTO] to analyze the validity of existing patents—violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury."[349] While the Federal Circuit summarily dismissed the *Oil States* case (i.e., without a written opinion), it previously rejected a constitutional challenge to inter partes review proceedings in a written decision.

Specifically, in *MCM Portfolio v. Hewlett-Packard*, the Federal Circuit addressed whether inter partes review proceedings violate (1) Article III of the Constitution, by delegating issues to the PTO that must be adjudicated by a federal court, and (2) the Constitution's Seventh Amendment because there is no jury in PTO proceedings.[350] Article III establishes the federal court system, providing that the "judicial Power shall extend to all Cases, in Law and Equity, arising under ... the Laws of the United States,"[351] while the Seventh Amendment provides: "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved...."[352] In rejecting the constitutional challenge, the Federal Circuit reasoned that:

> The patent right derives from an extensive federal regulatory scheme, and is created by federal law. Congress created the PTO, an executive agency with specific authority and expertise in the patent law, and saw powerful reasons to utilize the expertise of the PTO for an important public purpose—to correct the agency's own errors in issuing patents in the first place.... There is notably no suggestion that Congress lacked authority to delegate to the PTO the power to issue patents in the first instance. It would be odd indeed if Congress could not authorize the PTO to reconsider its own decisions.[353]

The Supreme Court denied certiorari in *MCM Portfolio*, while granting it in *Oil States*.

In its brief on the merits, filed on August 24, 2017, Oil States raises two main arguments. First, the company asserts that "[i]nter partes review impermissibly transfers the responsibility for deciding common-law suits from Article III judges to administrative agency employees who are beholden to Executive Branch officials—precisely the evil the Framers sought to avoid."[354] Second, Oil States contends that "[i]nter partes review impermissibly supplants juries as well as judges," in violation of the Seventh Amendment.[355] Greene's Energy Group's brief on the merits is currently due on October 23, 2017, while Oil States' reply is due November 20, 2017.

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[348] *See* discussion *supra* in *Major Patent Legislation*.

[349] 639 F. App'x 639 (Fed. Cir. 2016), cert. granted, No. 16-712 (June 12, 2017).

[350] 812 F.3d 1284 (Fed. Cir. 2015), cert. denied, 137 S. Ct. 292 (2016).

[351] U.S. CONST. art. III, § 2. For a discussion of the constitutional limits on Congress's ability to create non-Article III tribunals, *see* CRS Report R43746, *Congressional Power to Create Federal Courts: A Legal Overview*, by Andrew Nolan and Richard M. Thompson II.

[352] U.S. CONST. amend VII.

[353] MCM Portfolio, 812 F.3d at 1290–91 (internal quotation marks and citations omitted).

[354] Brief for Petitioner at 15, Oil States Energy Srvs. LLC v. Greene's Energy Grp. LLC, No. 16-712 (filed Aug. 24, 2017) [hereinafter Petitioner's Brief].

[355] *Id.* at 18.

There appears to be much anticipation as to the outcome of this case.[356] One commentator has stated that "[t]he Supreme Court's decision holds the potential to be one of the most significant patent decisions in decades."[357] In deciding this case, the Supreme Court must determine whether a patent is a *private property right*, like real property,[358] and therefore revocable only in an Article III tribunal, as opposed to a *public right* created by an administrative agency empowered to revoke that right.[359] Notably, the Patent Act itself contains a provision stating "patents shall have the attributes of personal property."[360] If the Court were to find that patents are private property rights and hold that inter partes review proceedings are unconstitutional, there would be a cascade of consequences for the U.S. patent regime.[361]

Among the possible consequences experts are currently discussing is the question of what will happen to patents that were invalidated in inter partes review proceedings. Since the proceedings began in 2012, the PTO has received approximately 7,000 petitions and, of the more than 1,500 final decisions it has issued, roughly 1,300 have invalidated at least some patent claims.[362] One commentator has framed the question this way: "'What happens to all those patents? Do they suddenly spring back to life?'"[363]

Relatedly, as discussed above, is the fact that the PTO invalidates patents through other administrative proceedings, including reexamination proceedings, which have been available since the 1980s.[364] In addition to the question of the fate of patents invalidated during inter partes

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[356] *See, e.g.*, Ryan Davis, *AIA Constitutionality Case Could Create Patent Law Chaos*, LAW360 ANALYSIS (June 13, 2017), https://www.law360.com/articles/933529/aia-constitutionality-case-could-create-patent-law-chaos ("'Everyone will be waiting with bated breath to see how this decision comes out.'" (quoting Eldora Ellison of Sterne Kessler Goldstein & Fox PLLC)).

[357] *Id.* (quoting Marshall Schmitt of Michael Best & Friedrich LLP).

[358] With regard to patents, but in the context of the Takings Clause, the Supreme Court has recently suggested that patent rights are akin to personal property rights:

> Nothing in this history [of the Takings Clause] suggests that personal property was any less protected against physical appropriation than real property. As this Court summed up in *James v. Campbell*, 104 U.S. 356, 358 (1882), a case concerning the alleged appropriation of a patent by the Government: "[A patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser."

Horne v. Dep't of Agric., 135 S. Ct. 2419, 2427 (2015).

[359] Accordingly, Oil States asserts that "[a] patent is emphatically a private property right, 'taken from the people, from the public, and made the private property of the patentee.'" Petitioner's Brief, *supra* note 355, at 16–17 (quoting United States v. Am. Bell Tel. Co., 128 U.S. 315, 370 (1888)). *See also* Davis, *supra* note 357 ("'It seems to me the main issue this is going to boil down to is whether patents should be treated as public rights or private rights.'" (quoting Joshua Goldberg of Finnegan Henderson Farabow Garrett & Dunner LLP)).

[360] 35 U.S.C. § 261 ("The [PTO] shall maintain a register of interests in patents and applications for patents and shall record any document related thereto upon request....").

[361] Davis, *supra* note 357 (stating that the *Oil States* case "could throw patent law into turmoil by derailing a system that has been used to challenge thousands of patents, while creating a host of new issues for courts to resolve"); Kenneth Hairston, *Why High Court Should Find IPR Constitutional*, LAW360 EXPERT ANALYSIS (June 16, 2017), https://www.law360.com/articles/935159/why-high-court-should-find-ipr-constitutional ("The case has provoked much consternation because the resulting decision carries the possibility of disrupting a system currently widely used to challenge patents, throwing into question previous Patent Trial and Appeal Board decisions as well as the PTAB's authority in reviewing future challenges.").

[362] *Id.*

[363] *Id.* (quoting Craig Countryman of Fish & Richardson PC).

[364] *See* discussion *supra* in *Administrative Proceedings Before the PTO*.

review proceedings is that of those invalidated during reexamination.[365] Further, if the Supreme Court rules that inter partes review proceedings are unconstitutional, this will call into question the constitutionality of the PTO's other revocation proceedings, including reexamination and post-grant reviews.

Finally, should the Court hold that inter partes review proceedings are unconstitutional, the question of the impact on the caseload of the federal courts looms large. As noted, about 7,000 petitions for inter partes review proceedings have been filed in the last five years.[366] While it is unlikely that all such petitions would amount to infringement complaints lodged in the federal courts, it seems likely that the elimination of PTO revocation proceedings will have a tangible effect on the dockets of the federal courts.

Notably, as of the date of this report, the only other patent case scheduled to be heard during the Court's October 2017 Term also involves inter partes review proceedings. In *SAS Institute v. Matal*, the Court granted certiorari to answer the following question:

> Does 35 U.S.C. § 318(a), which provides that the [PTAB] in an inter partes review "shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner," require that Board to issue a final written decision as to every claim challenged by the petitioner, or does it allow that Board to issue a final written decision with respect to the patentability of only some of the patent claims challenged by the petitioner, as the Federal Circuit held?[367]

Under current PTO practice, a petitioner may challenge a patent "on all or some of the challenged claims,"[368] and the PTO may institute a proceeding on a subset of the petition's challenged claims. Obviously, the challenge as to whether the PTO must address all patent claims challenged by a petitioner will become moot if the Court strikes down inter partes review proceedings as unconstitutional in *Oil States*. Standing alone, however, *SAS Institute* also has implications for the PTO because it has the potential to eliminate a practice of the agency that allows it to manage its workload by limiting the number of challenged claims it must analyze.

Legislative and Executive Patent Law Activity

As noted, patent reform appears to be of perennial concern to Congress.[369] For instance, prior to the enactment of the AIA in 2011, there were several years of legislative activity in this area.[370]

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[365] Davis, *supra* note 357 ("'You have to wonder if the Supreme Court calls IPRs into question, what that means for all the other proceedings'.... They would have the same constitutional deficiency, so they would be at risk, too.'" (quoting Craig Countryman of Fish & Richardson PC)).

[366] Id.

[367] 825 F.3d 1341 (Fed. Cir. 2016), cert. granted, No. 16-969 (U.S. May 22, 2017).

[368] 37 C.F.R. § 42.108(a).

[369] *See* Gugliuzza, *supra* note 9, at 332–33 ("[P]atent reform is now a staple of Congress's agenda, and that legislative activity surely piques the Court's interest."); *see also* Patent Legislation on the Hill: Senators Introduce the STRONGER Patents Act of 2017, ROPES & GRAY INTELLECTUAL PROPERTY ALERT (June 23, 2017), https://www.ropesgray.com/newsroom/alerts/2017/06/Patent-Legislation-on-the-Hill-Senators-Introduce-the-STRONGER-Patents-Act-of-2017.aspx ("Although the [AIA] was enacted less than six years ago, the appetite for intellectual property legislation in D.C. has continued unabated over the last several years. In addition to the recent Defend Trade Secrets Act (passed by Congress in 2016), there is a laundry list of recent introduced (but unenacted) bills implicating IP rights: the PATENT Act, the STRONG Patents Act, the TROL Act, the Innovation Act, the Trade Protection Not Troll Protection Act, the SHIELD Act, and the Stop Online Piracy Act—to name just a few.").

[370] *See, e.g.*, Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007); Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

With regard to patent reform, issues that have received attention include, but are not limited to: (1) remedies for patent infringement, including the availability of damages, injunctive relief, and attorney fees;[371] (2) administrative proceedings before the PTO, such as those enacted in the AIA; (3) the issue of non-practicing entities (i.e., patent trolls);[372] and (4) the high costs and burdens of patent litigation for U.S. businesses, and the costs that are passed on to consumers,[373] particularly in the drug context.[374]

Most recently, in the 115th Congress, the Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act (STRONGER Patents Act) of 2017 was introduced.[375] The bill's stated purpose is "to strengthen the position of the United States as the world's leading innovator by amending title 35 ... to protect the property rights of the inventors that grow the country's economy."[376] The bill contains many provisions of the Support Technology and Research for Our Nation's Growth Patents Act of 2015 (STRONG Patents Act) of the 114th Congress,[377] as well as provisions from the Targeting Rogue and Opaque Letters Act of 2015 (TROL Act).[378]

At center, the STRONGER Patent Act addresses the PTO's post-grant proceedings, with much of its provisions devoted to reforms of the inter partes review and post-grant review proceedings.[379] For example, the bill would align the PTO's patent claim construction standard with that of the federal courts.[380] The bill would also require that findings of patent invalidity by the PTO be

[371] *See, e.g.*, S. 1390, 115th Cong. (2017); H.R. 9, 114th Cong. § 3(b)(1); S. 1137, 114th Cong. § 7(a).

[372] O'Malley, *supra* note 7, at 5 ("A recent Government Accountability Office study estimates that about twenty percent of patent cases are prosecuted by non-practicing entities, though many argue that this estimate is low. This monetization of the property rights reflected in patents is new and results in enforcement of patents that in years past would have remained dormant—passive rights which owners either did not have the wherewithal or the desire to enforce. And some assert that it results in enforcing—or efforts to enforce—undeserving patents, which either should not have been granted or are no longer relevant." (footnotes omitted)). *See also* Gugliuzza, *supra* note 9, at 342 ("Despite the patent system's purpose to incentivize innovation, in some technological fields, the patent system today may be thwarting innovation because many patents represent minimal advances in the state of the art and provide poor notice of their boundaries. Those poor quality patents facilitate litigation, heavily concentrated in the ... Eastern District of Texas, in which patentees file suit with no intention of actually litigating; they are instead leveraging litigation costs to extract a quick settlement." (footnotes omitted)).

[373] O'Malley, *supra* note 7, at 7–8 ("The increase in patent litigation and the burdens imposed on businesses by it—especially litigation where abusive or coercive tactics are employed—come at the same time that the need for legitimate patent protection for true innovators has been heightened. As we have become less capable of competing in the manufacturing and energy sectors, American ingenuity has become a primary driver of our economy. It is our ability to conceive of better mousetraps, to continually be one step ahead in the technology space, and to lead in medical research and development, that keeps us competitive in the world. Thus, while complaints about patent litigation, and its attendant costs and burdens, abound, few would debate that a robust patent system—with meaningful mechanisms to enforce patent rights—is necessary to foster innovation and to protect the often substantial investments innovators must make.")

[374] *Id.* at 8 ("[T]hose conducting pharmaceutical research and development will tell you that the costs of developing, testing, and getting regulatory approval for new drugs is so prohibitive that it would not be undertaken but for the promise of patent protection, which offers at least the hope of recouping that outlay.").

[375] S. 1390, 115th Cong. (2017).

[376] *Id.*

[377] S. 632, 114th Cong. (2015).

[378] H.R. 2045, 114th Cong. (2015).

[379] S. 1390, 115th Cong. §§ 102–03.

[380] *Id.* §§ 102(a), 103(a) (harmonizing the claim construction standard used in PTO post-grant proceedings with the standard used in district court litigation).

proved by "clear and convincing" evidence, as they are in district court litigation.[381] With regard to standing in PTO proceedings, the bill would limit potential petitioners to only those individuals and enterprises who have a demonstrated adverse relationship to the challenged patent to the exclusion of nonpracticing entities (i.e., patent trolls).[382] In addition to provisions amending PTO administrative proceedings, Title II of the bill empowers the Federal Trade Commission to take certain enforcement actions against nonpracticing entities that send misleading patent-related demand letters.[383]

While addressing some of the concerns raised in the *Oil States* litigation with regard to inter partes review,[384] as one observer has noted, the bill may modify or overturn the holdings of at least five intellectual property-related Supreme Court cases from the past decade, including *eBay Inc. v. MercExchange*,[385] *Microsoft Corp. v. AT&T Corp.*,[386] *Global-Tech Appliances v. SEB SA*,[387] *Akamai Techs. v. Limelight Networks*,[388] and *Cuozzo Speed Techs. v. Lee*.[389] The future of the Bill remains to be seen, but it should be noted that similar patent reform legislation introduced in prior Congresses, such as the STRONG Patents Act of 2015, did not lead to enactment.

Finally, on the executive front, the central policy pronouncement related to patents and intellectual property issued since President Donald Trump took office was the initiation of an investigation into China's intellectual property practices, including patent protection. On August 14, 2017, President Trump issued a presidential memorandum directing the United States Trade Representative (USTR) to "determine ... whether to investigate any of China's laws, policies, practices, or actions that may be unreasonable or discriminatory and that may be harming American intellectual property rights, innovation, or technology development"[390] pursuant to section 301 of the Trade Act of 1974.[391] The USTR initiated such an investigation on August 18, 2017, and is scheduled to convene a public hearing on October 10, 2017.[392] While the investigation is in its early stages, it could result in remedial trade actions in response to a finding of unfair intellectual property practices, such as the suspension of trade agreement concessions or the imposition of duties or import quotas, among others.[393]

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[381] *Id.* §§ 102(b), 103(b).

[382] *Id.* §§ 102(c), 103(c).

[383] *Id.* tit. II.

[384] *See* discussion *supra* in *Viability of Inter Partes Review Proceedings*.

[385] 547 U.S. 388 (2006) (eliminating the presumption of injunctive relief in patent infringement cases).

[386] 550 U.S. 437 (2007) (discussing the presumption against extraterritoriality in the context of 35 U.S.C. § 271(f)).

[387] 563 U.S. 754 (2011) (defining the knowledge and intents requirements for induced infringement liability).

[388] 134 S. Ct. 2111 (2014) (discussing indirect infringement in the context of multiple actors).

[389] 136 S. Ct. 2131 (2016) (defining the standards for claim construction).

[390] Presidential Memorandum for the United States Trade Representative (Aug. 14, 2017), https://www.whitehouse.gov/the-press-office/2017/08/14/presidential-memorandum-united-states-trade-representative.

[391] 19 U.S.C. § 2411.

[392] Initiation of Section 301 Investigation; Hearing; and Request for Public Comments: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, 82 Fed. Reg. 40,213 (Aug. 24, 2017).

[393] 19 U.S.C. § 2411(c).

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